

SOLIGENIX, INC.  
Form S-1/A  
June 13, 2013

As filed with the Securities and Exchange Commission on June 13, 2013.  
Registration No. 333-184762

---

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 3  
TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware (State or other jurisdiction of incorporation or organization)	2834 (Primary Standard Industrial Classification Code Number)	41-1505029 (I.R.S. Employer Identification No.)
---	---	---

Soligenix, Inc.  
29 Emmons Drive, Suite C-10  
Princeton, New Jersey 08540  
(609) 538-8200

(Address, including zip code, and telephone number, including area code,  
of registrant's principal executive offices)

Christopher J. Schaber, Ph.D.  
President and Chief Executive Officer  
Soligenix, Inc.  
29 Emmons Drive, Suite C-10  
Princeton, New Jersey 08540  
(609) 538-8200

(Name, address, including zip code, and telephone number,  
including area code, of agent for service)

with copies to:

Leslie J. Croland, Esq.  
Duane Morris LLP  
Suite 3400  
200 South Biscayne Boulevard  
Miami, Florida 33131-2318

Barry I. Grossman, Esq.  
Lawrence A. Rosenbloom, Esq.  
Ellenoff Grossman & Schole LLP  
150 East 42nd Street, 11th Floor  
New York, New York 10017

(305) 960-2200

(212) 370-1300

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date hereof.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

---



Statement filed with the Securities and Exchange Commission on March 1, 2013.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

---

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted .

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION, DATED JUNE 13, 2013

SOLIGENIX, INC.

UP TO 5,405,405 UNITS, EACH CONSISTING OF  
ONE SHARE OF COMMON STOCK,  
A WARRANT TO PURCHASE UP TO AN ADDITIONAL 0.75 SHARE OF COMMON STOCK AND A  
PREFERRED  
STOCK PURCHASE RIGHT

We are offering up to 5,405,405 units on a “best efforts” basis, with each unit consisting of (i) one share of our common stock, (ii) a warrant to purchase up to an additional 0.75 share of our common stock, and (iii) a preferred stock purchase right issuable in accordance with the Rights Agreement, dated June 22, 2007, between us and American Stock Transfer & Trust Company, which are attached to and trade with our common stock. The warrants entitle holders to purchase 0.75 share of our common stock for each warrant they hold at a price equal to \_\_\_\_\_% of the price of each unit. The units will separate immediately and the common stock and warrants will be issued separately and the common stock will trade separately; however until exercised the preferred stock purchase rights will trade with the shares of common stock to which such rights are presently attached. Each preferred stock purchase right entitles the registered holder to purchase one one-thousandth of a share of our Series A Junior Preferred Stock at a price of \$3.70 per one one-thousandth of a share, subject to certain adjustments. We are not required to sell any specific dollar amount or number of units. We and the placement agent may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.

Our common stock is listed on the OTCQB market under the symbol “SNGX”. We do not intend to apply for listing of the warrants on any securities exchange. On June 11, 2013, the last quoted sale price of our common stock as reported on the OTCQB was \$1.85 per share.

Investing in our securities involves significant risks, including those set forth in the “Risk Factors” section of this prospectus beginning on page 6.

	Per unit	Total
Offering Price	\$ 1.85	\$ 10,000,000
Placement Agent’s Fees	\$ 0.13	\$ 720,000
Placement Agent’s Fees (officers, directors and company investors)	\$ 0.01	\$ 28,000
Offering Proceeds before expenses	\$ 1.71	\$ 9,252,000

Maxim Group LLC has agreed to act as our placement agent in connection with this offering. In addition, we or the placement agent may engage one or more sub placement agents or selected dealers. The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of units, but will assist us in this offering on a “best efforts” basis. We have agreed to pay the placement agent a cash fee equal to (i) 8% of the gross proceeds received by investors who purchase units in the offering that are contacted by the placement agent, (ii) 4% of the gross proceeds received from our officers or directors (in excess of the first \$300,000 of gross

proceeds received from such officers and directors) or from certain investors with which we have a previous relationship and (iii) \$25,000 upon the execution of the engagement letter with the placement agent. Additionally, we have agreed to issue the placement agent “placement agent warrants” to purchase shares of our common stock equal to 5% of the aggregate number of shares of common stock included in units sold in the offering (excluding shares sold to our officers or directors). The placement agent warrants will have terms substantially similar to the warrants included in units offered hereby but provide for a cashless exercise feature. We estimate the total expenses of this offering, excluding the placement agent’s fees, will be approximately \$283,000. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See “Plan of Distribution” beginning on page 51 of this prospectus for more information on this offering and the placement agent arrangements.

The offering expires on the earlier of (i) the date upon which all of the units being offered have been sold, or (ii) July 31, 2013. We may decide to terminate the offering at any time without further notice to investors. All costs associated with the registration will be borne by us. Pursuant to an escrow agreement among us, the placement agent and U.S. Bank, N.A., as escrow agent, some or all of the funds received in payment for the units sold in this offering will be wired to a non-interest bearing escrow account and held until we and the placement agent notify the escrow agent that this offering has closed.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Placement Agent

Maxim Group LLC

The date of this prospectus is \_\_\_\_\_, 2013

---

Table of Contents

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	1
PROSPECTUS SUMMARY	2
RISK FACTORS	6
USE OF PROCEEDS	14
DIVIDENDS	14
DILUTION	15
BUSINESS	17
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	34
MANAGEMENT	40
EXECUTIVE COMPENSATION	44
SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT	48
TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS	50
PLAN OF DISTRIBUTION	51
DESCRIPTION OF SECURITIES	53
MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	56
DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES	56
EXPERTS	57
LEGAL MATTERS	57
AVAILABLE INFORMATION	57
INDEX TO FINANCIAL STATEMENTS	F-1

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information.

We have not authorized the placement agent or any underwriters, brokers or dealers to make an offer of the units in any jurisdiction where the offer is not permitted.

You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of this prospectus.

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The information contained in this prospectus, including the information incorporated by reference into this prospectus, includes forward-looking statements. These forward-looking statements are often identified by words such as "may," "will," "expect," "intend," "anticipate," "believe," "estimate," "continue," "plan," "potential" and similar expressions. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including:

our dependence on the expertise, effort, priorities and contractual obligations of third parties in the clinical trials, manufacturing, marketing, sales and distribution of our products;

the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our proposed products, including: (i) the timing, status and results of our or our commercial partners' filings with the U.S. Food and Drug Administration and its foreign equivalents, (ii) the timing, status and results of non-clinical work and clinical studies, including regulatory review thereof and (iii) the heavily regulated industry in which we operate our business generally;

significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;

uncertainty as to whether our technologies will be safe and effective to support regulatory approvals;

our ability to obtain future financing or funds when needed, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;

that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;

our ability to obtain further grants and awards from the U.S. Government and other countries, and maintenance of our existing grants;

our ability to enter into any biodefense procurement contracts with the U.S. Government or other countries;

our ability to patent, register and protect our technology from challenge and our products from competition;

maintenance or expansion of our license agreements with our current licensors;

the protection and control afforded by our patents or other intellectual property, and any interest in patents or other intellectual property that we license, or our or our partners' ability to enforce our rights under such owned or licensed patents or other intellectual property;

changes in healthcare regulation;

changes in the needs of biodefense procurement agencies;



maintenance and progression of our business strategy;

the possibility that our products under development may not gain market acceptance;

our expectations about the potential market sizes and market participation potential for our approved or proposed products;

our expected revenues (including sales, milestone payments and royalty revenues) from our products or product candidates and any related commercial agreements of ours;

the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to address any regulatory issues that have arisen or may in the future arise; and

competition existing today or that may arise in the future, including the possibility that others may develop technologies or products superior to our products.

You should also consider carefully the statements under "Risk Factors" and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements and could materially and adversely affect our business, operating results and financial condition. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements.

The forward-looking statements speak only as of the date on which they are made, and, except to the extent required by federal securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. For a more complete understanding of this offering, you should read the entire prospectus carefully, including the risk factors and the financial statements. References in this prospectus to “we,” “us,” “our,” and “Soligenix” refer to Soligenix, Inc. You should read both this prospectus together with additional information described below under the heading “Available Information.”

About Our Company

We are a clinical stage biopharmaceutical company that is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate (“BDP”) for the prevention/treatment of gastrointestinal (“GI”) disorders characterized by severe inflammation, including pediatric Crohn’s disease (SGX203), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator (“IDR”) technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding. We also recently announced a global and exclusive collaboration with Intrexon Corporation (“Intrexon”) through which we intend to develop and commercialize human monoclonal antibody therapies to treat melioidosis.

An outline for our business strategy follows:

Complete a Phase 1 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;

Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;

Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic graft-versus-host disease (“GVHD”);

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

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

Explore other business development and merger/acquisition strategies, an example of which is our recently announced collaboration with Intrexon.



Table of Contents

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

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX942	Oral Mucositis in Head and Neck Cancer	IND clearance and Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014
SGX203	Pediatric Crohn's disease	Phase 1 clinical trial initiated, with data expected in the first half of 2013; Phase 2/3 clinical trial planned for the second half of 2013, with data expected in the second half of 2014
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated; Phase 2 trial planned for the first half of 2014, with data expected in the first half of 2015
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014

Vaccine Thermostability Platform

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

BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated; Phase 2 trial planned for the first half of 2014
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical;

		Phase 1 clinical trial planned for second half of 2014
OrbeShield™	Therapeutic against GI ARS	Follow-on pre-clinical study initiated; Initial pre-clinical study complete; protection observed in canines
SGX943/SGX101	Melioidosis	Pre-clinical

#### Recent Developments

The following are certain recent developments relating to our company:

On June 3, 2013, we announced that our SGX942 development program for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients has received “Fast Track” designation from the U.S. Food and Drug Administration (“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.

On May 22, 2013, we announced that the U.S. Patent and Trademark Office granted patent 8,444,991 titled “Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition.” The new patent’s claims encompass composition of matter and method claims for ThermoVax™, our vaccine thermostabilization technology exclusively licensed to us by the University of Colorado.

On May 14, 2013, we announced the initiation of a Phase 1 clinical trial for development of SGX203 (oral BDP) for the treatment of pediatric Crohn’s disease. The objective of the trial is to determine the pharmacokinetic and pharmacodynamic profile of oral BDP in healthy young male and female adolescents and adults. We expect that this study will enroll 24 subjects and that assessments will be completed in June 2013. We previously received “Fast Track” and orphan drug designations from the FDA for oral BDP as a treatment for pediatric Crohn’s Disease.

On May 1, 2013, we announced the formation of a global exclusive channel collaboration between us and Intrexon through which we intend to develop and commercialize human monoclonal antibody therapies for a new biodefense and infectious disease application using Intrexon’s advanced human antibody discovery, isolation, and production technologies. The target of the channel collaboration will be melioidosis, a potentially lethal disease caused by the Gram-negative bacteria *Burkholderia pseudomallei*, which is endemic in Southeast Asia and Northern Australia. It is also considered a high-priority biodefense threat as defined in the 2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy established by the U.S. Department of Health and Human Services (“DHHS”) with the potential for widespread dissemination through aerosol.

On March 27, 2013, we announced that the FDA completed its review and cleared the Investigational New Drug (“IND”) application for SGX942 for the treatment of oral mucositis resulting from radiation and/or chemotherapy treatment in head and neck cancer patients. This clearance allows us to initiate a Phase 2, randomized, double-blind, placebo-controlled, dose-escalating clinical study of SGX942 in patients being treated for head and neck cancer, which trial is expected to be initiated in the second half of 2013.

On March 19, 2013, we announced key progress in the development of ThermoVax™, our proprietary vaccine thermostabilization technology. Several complementary preclinical studies have indicated the potential for high temperature stability for a minimum of six months and increased potency of subunit vaccines formulated with ThermoVax™. These studies have been conducted with our proprietary ricin toxin vaccine (RiVax™) and anthrax vaccine (VeloThrax™) as part of a continuing program to evaluate the effectiveness of protein subunit vaccines to withstand extremes of temperature and other environmental stress conditions. The research and development of ThermoVax™ is being supported by a \$9.4 million National Institute of Allergy and Infectious Disease grant to us for biodefense vaccines to prevent ricin toxin and anthrax exposure.

On February 20, 2013, we announced the submission of a full contract proposal to the Biomedical Advanced Research and Development Authority's Division of Chemical, Biological, Radiological and Nuclear Medical Countermeasures. This submission supports a potential multi-year, multi-million dollar contract to develop OrbeShield™ as a medical countermeasure (MCM) for the treatment of GI ARS.

Table of Contents

On January 29, 2013, we announced that our OrbeShield™ development program for the treatment of GI ARS received "Fast Track" designation from the FDA.

On January 4, 2013, we announced that the FDA completed its review and cleared our IND application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS.

On January 2, 2013, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to OrbeShield™ for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

On December 28, 2012, we announced that we received approximately \$521,000, net of transaction costs, in non-dilutive financing via the State of New Jersey's Technology Business Tax Certificate Transfer Program.

On December 27, 2012, we announced that we regained the North American and European commercial rights to oral BDP through an amendment of our Collaboration and Supply Agreement with Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau"). We are now free to commercialize or enter into commercialization agreements for our oral BDP suite of products with other parties without limitation.

On December 18, 2012, we announced the acquisition of a novel drug technology, referred to as SGX94, representing a novel approach to modulation of the innate immune system. As part of the acquisition, we acquired all rights to SGX94, including composition of matter patents, and preclinical and Phase 1 clinical study datasets for SGX94, which is poised to enter Phase 2 clinical testing in humans.

Corporate Information

We were incorporated in Delaware in 1987 under the name Immunotherapeutics Inc. 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.

Table of Contents

Summary of the Offering

Securities Offered	Up to 5,405,405 units. Each unit will consist of (i) one share of our common stock, (ii) a warrant to purchase up to an additional 0.75 share of our common stock, and (iii) a preferred stock purchase right issuable in accordance with the Rights Agreement, dated June 22, 2007, between us and American Stock Transfer & Trust Company, which are attached to and trade with our common stock. Each preferred stock purchase right entitles the registered holder to purchase one one-thousandth of a share of our Series A Junior Preferred Stock at a price of \$3.70 per one one-thousandth of a share, subject to certain adjustments. Units may be issued and sold in one or more closings up to the termination date, July 31, 2013.
Offering Price	\$1.85 per unit.
Description of Warrants	The warrants will be exercisable at any time during the period commencing after the date of closing and ending on the fifth anniversary of the closing date at an exercise price per share equal to _____% of the price of each unit. We and the placement agent may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.
Common Stock Outstanding Prior to the Offering	12,231,492 shares.
Common Stock Outstanding After the Offering	17,636,897 shares, which does not include 4,054,054 shares of common stock issuable upon exercise of the warrants included in the offered units.
Use of Proceeds	We expect to use the proceeds received from the offering to further develop our products and product candidates and for general working capital purposes.
OTCQB Symbol	SNGX
Risk Factors	See “Risk Factors” beginning on page 6 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in the units.
Additional Terms	We reserve the right, in our sole discretion and without prior notice to other investors, to offer certain investors in the offering additional rights and preferences, including, without limitation, board nomination rights. We will not, however, offer investors different pricing terms for the securities offered hereby.

The total number of shares of our common stock outstanding as of the date of this prospectus was 12,231,492, which excludes the following:



137,211 shares of common stock reserved for future issuance under our equity incentive plans. As of the date of this prospectus, there were options to purchase 1,446,474 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$3.14 per share;

2,843,338 shares of common stock issuable upon exercise of outstanding warrants as of the date of this prospectus with a weighted average exercise price of \$3.13 per share; and

4,054,054 shares of common stock that will be issuable upon exercise of warrants at an exercise price of \$\_\_\_\_\_ per share sold as part of the units in this offering and up to 270,271 shares of common stock that will be issuable upon exercise of the placement agent warrants at an exercise price of \$\_\_\_\_\_ per share, assuming all of the units are sold in this offering and that none of our officers and directors purchase units in this offering.

Table of Contents

RISK FACTORS

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

Risks Related to Our Business

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

We have experienced significant losses since inception and, at March 31, 2013, had an accumulated deficit of approximately \$123.4 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of March 31, 2013, we have approximately \$2.6 million in cash available. Based on our projected budgetary needs and funding from existing grants over the next two years, we expect to be able to maintain the current level of our operations into the second quarter of 2014.

We have sufficient funds through our existing biodefense grant facilities from the 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 and recently received an additional Small Business Innovation and Research (“SBIR”) grant from NIAID for \$600,000. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component, which is approximately 21% above our subcontracted expenses, will finance some fixed costs for direct employees working on the grants and other administrative costs.

Our products are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. From inception through March 2013, we have expended approximately \$47.5 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least \$3 million over the next two years in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs.

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

In order to generate revenues and profits, our organization must, along with corporate partners and collaborators, positively research, develop, manufacture and commercialize our technologies or product candidates. Our current

product candidates are in various stages of early clinical and pre-clinical development and will require significant further funding, research, development, pre-clinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

we may not be able to maintain our current research and development schedules;

Table of Contents

we may be unable to secure procurement contracts on beneficial economic terms or at all from the U.S. government or others for our biodefense products;

we may encounter problems in clinical trials; or

the technology or product may be found to be ineffective or unsafe.

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 develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of any other technology we develop, even if it is shown to be effective, if:

it is not economical or the market for the product does not develop or diminishes;

we are not able to enter into arrangements or collaborations to manufacture and/or market the product;

the product is not eligible for third-party reimbursement from government or private insurers;

others hold proprietary rights that preclude us from commercializing the product;

we are not able to manufacture the product reliably;

others have brought to market similar or superior products; or

the product has undesirable or unintended side effects that prevent or limit its commercial use.

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

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

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. We estimate that the clinical trials of our product candidates that we have planned will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Favorable results in early studies or trials, if any, may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing, Phase 1 and Phase 2 clinical trials does not ensure that later Phase 2 or Phase 3 clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing. In addition, we, the FDA or other regulatory authorities may suspend clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or the FDA or other regulatory authorities find deficiencies in our submissions or conduct of our trials. For example, our confirmatory Phase 3 clinical trial for orBec® (oral BDP) in the treatment of GI GVHD was stopped on September 15, 2011 at the recommendation of an independent Data Safety Monitoring Board (“DSMB”) as it was highly unlikely to achieve the predetermined end point of efficacy based on the interim results. Although no safety concerns were raised by the DSMB, preliminary findings indicated that there were no significant differences

between the orBec ® group and placebo group for the primary endpoint or for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, we terminated the development of orBec ® for the treatment of acute GI GVHD. Although we hope to obtain FDA approval for oral BDP in similar indications, such as treatment of chronic GI GVHD, treatment of pediatric Crohn's disease, acute radiation enteritis, and GI ARS, there can be no assurances that the FDA will ever approve oral BDP for market launch in any of these indications.

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

## Table of Contents

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, injunctions or other 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 are and will be dependent on government funding, which is inherently uncertain, in order to progress 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 other governmental agencies, the viability of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our receipt of government funding is also dependent on our ability to adhere to the terms and provisions of the original grant documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for grants we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business.

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

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards, which material will be used in

clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to be able to develop, produce, secure regulatory approval of and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

## Table of Contents

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

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

We do not have sales and marketing experience and our lack of experience may restrict our ability to commercialize some of our product candidates.

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

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

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to 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.

The technology on which our channel partnering arrangement with Intrexon is based on is early stage technology in the field of Melioidosis.

Our exclusive channel collaboration arrangement with Intrexon contemplates the use of Intrexon’s modular genetic engineering platform for the development of active pharmaceutical ingredients and drug products targeting the biodefense countermeasure, melioidosis. Such technology has a limited history of use in the design and development of human therapeutic product candidates and may therefore involve unanticipated risks or delays. Although we plan to leverage Intrexon’s technology and scientific expertise to develop products for the treatment of melioidosis, an infectious disease caused by bacteria found in soil and water, we may not be successful in developing and commercializing these products for a variety of reasons. The risk factors set forth herein that apply to our other



product candidates, which are in various stages of development, also apply to product candidates that we seek to develop under our exclusive channel partnership with Intrexon.

We will incur additional expenses in connection with our exclusive channel collaboration arrangement with Intrexon.

Pursuant to our exclusive channel collaboration with Intrexon, we are responsible for future research and development expenses of product candidates developed under such collaboration. Although it is our intent to pursue government funding to support this development, we expect the level of our overall research and development expenses going forward will increase. Because our collaboration with Intrexon is new, we have yet to assume development responsibility and costs associated with such program. In addition, because development activities are determined pursuant to a joint steering committee comprised of representatives from Intrexon and our company, future development costs associated with this program may be difficult to anticipate and exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaboration due to lack of sufficient government funding or our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain funding, we may be forced to seek licensing partners or discontinue development.

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.

Table of Contents

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. Moreover, the passage of the Patient Protection and Affordable Care Act in 2010, and efforts to amend or repeal such law, has created significant uncertainty relating to the scope of government regulation of healthcare and related legal and regulatory requirements, which could have an adverse impact on sales of our products.

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

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

We currently rely on license agreements from the University of Texas Southwestern Medical Center, the University of British Columbia, Harvard University, the University of Colorado, and George B. McDonald, MD for the rights to commercialize key product candidates, and we recently entered into an exclusive channel collaboration agreement with Intrexon pursuant to which we acquired a license to Intrexon's advanced human antibody discovery, isolation, and production technologies. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, if at all.

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

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

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

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of \$5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

## Table of Contents

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

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

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

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

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

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

It is also possible that our owned or licensed technologies may infringe on patents or other rights owned by others, and licenses to which may not be available to us. We may be unable 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.

## Table of Contents

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

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

During recent months, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment and the potential impact of the so-called “fiscal cliff” arising from the combination of tax increases and automatic spending cuts scheduled to take effect at the end of calendar 2012 and in early calendar 2013 in the U.S. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by current and future economic conditions. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows.

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

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to potential market size, patient population, clinical trial enrollment or data dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific business as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

### 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;

Table of Contents

economic and other external factors; and  
general market conditions.

Since January 1, 2012, the closing stock price (split adjusted) has fluctuated between a high of \$2.05 per share to a low of \$0.23 per share. As of June 11, 2013, our common stock closed at \$1.85 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 our common stock, as well as potential sale of common stock by the holders of warrants and options, could have an adverse effect on the market price of our shares.

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

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

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

Shareholders may suffer substantial dilution related to issued stock warrants and options, and our outstanding stock warrants and options may have an adverse effect on the market price of our common stock.

As of March 31, 2013, we had a number of agreements or obligations that may result in dilution to investors. These include:

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

options to purchase approximately 1,454,755 shares of our common stock at a current weighted average exercise price of approximately \$3.20.

We also established an incentive compensation plan for our management, employees and consultants. We have granted, and expect to grant in the future, options to purchase shares of our common stock to our directors, employees



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

There are also warrants being issued as part of this offering.

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

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

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

## Table of Contents

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.

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

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

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

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

We may use these proceeds in ways with which investors may not agree.

We have considerable discretion in the application of the proceeds of this offering. Investors will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used in a manner agreeable to you. You must rely on our judgment regarding the application of the net proceeds of this offering. The net proceeds may be used for corporate purposes that do not improve our profitability or increase the price of our shares. The net proceeds may also be placed in investments that do not produce income or that lose value.

## USE OF PROCEEDS

We estimate that we will receive up to \$8,968,654 in net proceeds from the sale of units in this offering, based on an assumed price of \$1.85 per unit and after deducting estimated placement agent’s fees and estimated offering expenses payable by us. We will use the net proceeds from this offering to further develop our products and product candidates and for working capital and other general corporate purposes. We will have broad discretion over the use of proceeds from this offering.

## 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.

## DILUTION

If you purchase units in this offering, and assuming no value is attributed to the warrants and no value is attributed to the preferred stock purchase right, your interest will be diluted immediately to the extent of the difference between the assumed public offering price of \$1.85 per unit and the as adjusted net tangible book value per share of our common stock immediately following this offering.

Our net tangible book value as of March 31, 2013 was approximately \$1.8 million, or approximately \$0.16 per share. Net tangible book value per share represents our total tangible assets less total tangible liabilities, divided by the number of shares of common stock outstanding as of March 31, 2013.

Table of Contents

Net tangible book value dilution per unit to new investors represents the difference between the amount per unit paid by purchasers in this offering and the as adjusted net tangible book value per share of common stock immediately after completion of this offering, assuming that no value is attributed to the warrants and the preferred stock purchase rights. After giving effect to our sale of up to 5,405,405 units in this offering at an assumed public offering price of \$1.85 per unit, and after deducting the placement agent's commission and estimated offering expenses, our as adjusted net tangible book value as of March 31, 2013 would have been approximately \$10.7 million, or \$0.65 per share. This represents an immediate increase in net tangible book value of \$0.49 per share to existing stockholders and an immediate dilution in net tangible book value of \$1.20 per unit to purchasers of units in this offering, as illustrated in the following table:

Assumed public offering price per unit	\$ 1.85
Net tangible book value per share as of March 31, 2013	\$ 0.16
Increase in net tangible book value per unit attributable to new investors	\$ 0.49
Adjusted net tangible book value per share as of March 31, 2013, after giving effect to the offering	\$ 0.65
Dilution per unit to new investors in the offering	\$ 1.20

The above discussion and table do not include the following:

132,680 shares of common stock reserved for future issuance under our equity incentive plans. As of March 31, 2013, there were options to purchase 1,454,755 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$3.20 per share;

1,034,483 shares of common stock issued to Intrexon on April 27, 2013 as consideration for the execution and delivery of a collaboration agreement;

2,843,338 shares of common stock issuable upon exercise of outstanding warrants as of March 31, 2013 with a weighted average exercise price of \$3.13 per share; and

4,054,054 shares of common stock that will be issuable upon exercise of warrants at an exercise price of \$\_\_\_\_\_ per share sold as part of the units in this offering.

Table of Contents

BUSINESS

Overview

We are a clinical stage biopharmaceutical company that is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate (“BDP”) for the prevention/treatment of gastrointestinal (“GI”) disorders characterized by severe inflammation, including pediatric Crohn’s disease (SGX203), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec ®), as well as developing our novel innate defense regulator (“IDR”) technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding. We also recently announced a global and exclusive collaboration with Intrexon Corporation (“Intrexon”) through which we intend to develop and commercialize human monoclonal antibody therapies to treat melioidosis.

An outline for our business strategy follows:

Complete a Phase 1 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;

Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;

Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic graft-versus-host disease (“GVHD”);

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

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

Explore other business development and merger/acquisition strategies, an example of which is our recently announced collaboration with Intrexon.

We were incorporated in Delaware in 1987. 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.

Table of Contents

Our Products in Development

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

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX942	Oral Mucositis in Head and Neck Cancer	IND clearance and Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014
SGX203	Pediatric Crohn's disease	Phase 1 clinical trial initiated, with data expected in the first half of 2013; Phase 2/3 clinical trial planned for the second half of 2013, with data expected in the second half of 2014
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated Phase 2 trial planned for the first half of 2014, with data expected in the first half of 2015
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014

Vaccine Thermostability Platform

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

BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated Phase 2 trial planned for the first half of 2014
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2014
OrbeShield™	Therapeutic against GI ARS	Follow-on pre-clinical study initiated; Initial pre-clinical study complete; protection observed in canines
SGX943/SGX101	Melioidosis	Pre-clinical

BioTherapeutics Overview

SGX94

In December 2012, we acquired a novel drug technology, we refer to as SGX94, representing what we believe is a novel approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. As part of the acquisition, we acquired all rights, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94. We also assumed a license agreement with the University of British Columbia (“UBC”) to advance the research and development of the SGX94 technology. The license agreement with UBC provides us with exclusive worldwide rights to manufacture, distribute, market sell and/or license or sublicense products derived or developed from this technology.



## Table of Contents

SGX94 is the research name for the active ingredient in SGX942, which is the research name for the finished drug product being studied in oral mucositis. It is a new class of short, synthetic peptides known as IDRs that have a novel mechanism of action in that it is simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. IDRs provide a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, sequestosome-1, also known as p62, which has a pivotal function in signal transduction during activation and control of the innate defense system. Preclinical data indicate that IDRs are active in models of a wide range of therapeutic indications including life-threatening bacterial infections as well as the severe side-effects of chemo- and radiation-therapy.

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

SGX94 has demonstrated efficacy in numerous animal disease models including mucositis, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. SGX94 showed a strong safety profile when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. SGX94 is the subject of an open Investigational New Drug (“IND”) application which has been cleared by the FDA. Market opportunities include, but are not limited to, mucositis, acute bacterial skin and skin structure infections, acinetobacter, melioidosis, acute radiation syndrome and as a vaccine adjuvant, with potential opportunities for non-dilutive funding to support the development.

We believe the potential worldwide market for SGX942 is in excess of \$500 million for all applications, including oral mucositis.

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

SGX942 is poised to start a Phase 2 clinical study in oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA in the first half of 2013. Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast Track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit a New Drug Application (“NDA”) for SGX942 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review, which implies an abbreviated review time of six months.

### About Oral Mucositis

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

duration of cancer treatment, leading to sub-optimal treatment outcomes.

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

We estimate, based upon our review of historic published studies and reports and an interpolation of data on the incidence of oral mucositis, that oral mucositis is a subpopulation of approximately 90,000 patients in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (>80% incidence of severe mucositis) and is common (40-100% incidence) in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

## Table of Contents

### Oral BDP

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

Based on its pharmacological characteristics, oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent 8,263,582 claiming the use of oral BDP as a method of treating inflammatory disorders of the gastrointestinal tract, including Crohn's disease, and an issued U.S. patent 6,096,731 claiming the use of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD following hematopoietic cell transplantation, as well as GVHD which also occurs following organ allograft transplantation. We also have European Patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract. We are planning to pursue development programs in the treatment of pediatric Crohn's disease, acute radiation enteritis, chronic GI GVHD and GI ARS pending further grant funding. We are also exploring the possibility of testing oral BDP for local inflammation associated with Ulcerative Colitis, among other indications.

We believe the potential worldwide market for oral BDP is in excess of \$500 million for all GI applications, namely, pediatric Crohn's disease, radiation enteritis, GI ARS, and chronic GI GVHD.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, oral BDP would benefit from orphan drug designations in the U.S. and in Europe. Orphan drug designations provide for 7 and 10 years of market exclusivity upon approval in the U.S. and Europe, respectively.

### SGX203 –for Treating Pediatric Crohn's Disease

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

### About Pediatric Crohn's Disease

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

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



## Table of Contents

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

### SGX201 –for Preventing Acute Radiation Enteritis

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

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

### About Acute Radiation Enteritis

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

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Some patients may develop dehydration and require hospitalization. With diarrhea, the gastrointestinal tract does not function normally, and nutrients such as fat, lactose, bile salts, and vitamin B 12 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.

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



## Table of Contents

### orBec® –for Treating Chronic GI GVHD

orBec® is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP to treat the gastrointestinal manifestation of chronic GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs such as prednisone to treat chronic GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. orBec® has been awarded orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD. In September 2012, we received a \$300,000 two-year SBIR grant awarded by the NIH to support a Phase 2 study for the treatment of chronic GI GVHD.

### About Chronic GVHD

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

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

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

We estimate, based upon our review of historic published studies and reports and an interpolation of data on the incidence of chronic GVHD, there to be 6,000 patients annually in the U.S., with a comparable number in Europe that suffer from chronic GVHD.

### Vaccines/BioDefense Overview

#### ThermoVax™ – Thermostability Technology

Our thermostability technology, ThermoVax™, is a novel method of rendering aluminum salt (known colloquially as Alum), adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax™ lies in its potential ability to eliminate the need for cold-chain production, transportation, and storage for Alum adjuvanted vaccines. This would relieve companies of the high costs of producing and maintaining vaccines under refrigerated conditions. Based on historical reports from the World Health Organization and other scientific reports, a meaningful proportion of vaccine doses globally are wasted due to excursions from required cold chain temperature ranges. This is due to the fact that most Alum adjuvanted vaccines need to be maintained at between 2 and 8 degrees Celsius and even brief excursions from this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability

programs specific for the vaccine lots in question. The savings realized from the elimination of cold chain costs and related product losses would in turn significantly increase the profitability of vaccine products. Elimination of the cold chain would also further facilitate the use of these vaccines in the lesser developed parts of the world. ThermoVax™ has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

ThermoVax™ development is being supported pursuant to our \$9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax™) and anthrax (VeloThrax™) vaccines. Proof-of-concept preclinical studies with ThermoVax™ indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with our aluminum-adjuvanted ricin toxin vaccine, RiVax™, made under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the ricin A chain, the immunogenic compound of the vaccine. When RiVax™ was kept at 40 degrees C for six months, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. Confirmatory results have extended the stability to six months when the vaccine is kept at 40 degrees C. In contrast, animals that were vaccinated with the liquid RiVax™ vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C.



## Table of Contents

Near term progress with ThermoVax™ will allow us to seek out potential partnerships with companies marketing FDA/ex-U.S. health authority approved Alum adjuvanted vaccines that are interested in eliminating the need for cold chain for their products. ThermoVax™ will further enable Soligenix to expand its vaccine development expertise beyond biodefense into the infectious disease space and also has the potential to allow for the development of multivalent vaccines (e.g., combination ricin-anthrax vaccine).

ThermoVax™ is the subject of U.S. patent number 8,444,991 issued on May 22, 2013 titled “Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition” and also U.S. patent application number 13/474,661 filed May 17, 2012 titled “Thermostable Vaccine Compositions and Methods of Preparing Same.” These patents and their corresponding foreign filings are licensed to Soligenix by the University of Colorado (“UC”), and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers thermostable vaccines for biodefense as well as other potential vaccine indications.

### RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first ricin vaccine. With RiVax™, we are a world leader in ricin toxin vaccine research. The immunogen in RiVax™ induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin. Two Phase 1 human clinical trials have been completed. The development of RiVax™ has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to Soligenix and to the University of Texas Southwestern Medical Center (“UTSW”) where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. Soligenix and UTSW have collectively received approximately \$25 million in grant funding from the NIH for RiVax™. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies anticipated to protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial, sponsored by UTSW, evaluated a more potent formulation of RiVax™ that contained an aluminum adjuvant (Alum), was completed in September 2012. The results of the Phase 1B study indicated that Alum adjuvanted RiVax™ was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax™. The outcomes of this second study were published in the Clinical and Vaccine Immunology (Vitetta et al., 2012, Recombinant Ricin Vaccine Phase 1B Clinical Trial, Clin. Vaccine Immunol. 10:1697-9). We have adapted the original manufacturing process for the immunogen contained in RiVax™ for large scale manufacturing and are further establishing correlates of the human immune response in non-human primates.

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



## Table of Contents

Assuming development efforts are successful for RiVax™, we believe potential government procurement contract(s) could reach \$200 million.

### About Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigations Bioterror report released in November 2007 titled Terrorism 2002-2005, which states that “Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations.”

([http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02\\_05.pdf](http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf))

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

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

### VeloThrax™ – Anthrax Vaccine

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

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

VeloThrax™’s greater immunogenicity could lead to a vaccine that can be administered in the fewest possible doses to induce the highest level of toxin neutralizing antibodies. Utilizing ThermoVax™, we believe that we will be able to develop VeloThrax™ into a vaccine with an improved stability profile, an issue that has proven challenging in the development of other anthrax vaccines. Extended stability at ambient temperatures would be a significant improvement for stockpiled vaccines and one which is not expected from conventional vaccines. Further, a

large-scale, cGMP production methodology has already been completed. Assuming long-term stability can be met, VeloThrax™ could be stockpiled for general prophylactic as well as a post exposure use.

## Table of Contents

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

Assuming development efforts are successful for VeloThrax™, we believe potential government procurement contract(s) could reach \$500 million.

### About Anthrax

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

### OrbeShield™ –for Treating GI ARS

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

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

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. This is the same type of toxicity that occurs in Soligenix’s acute radiation enteritis clinical program with SGX201. As a result, there is a dual avenue of development for Soligenix, and OrbeShield™ is potentially a “dual use”

compound, a desirable characteristic which is a specific priority of Biomedical Advanced Research and Development Authority (“BARDA”) for ARS and other medical countermeasure indications. BARDA recently invited Soligenix to submit a full contract proposal for a potential multi-year, multi-million dollar contract to develop OrbeShield™ from its current level of technical readiness to potential FDA approval. In response, Soligenix submitted its contract proposal in February 2013. We expect a response in the second half of 2013.

## Table of Contents

The FDA has cleared the IND application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS. Previously, development of OrbeShield™ had been largely supported by a \$1 million NIH grant to Soligenix's academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, we received an SBIR grant from NIAID of approximately \$600,000 to support further preclinical development of OrbeShield™ for the treatment of acute GI ARS. The FDA has awarded OrbeShield™ Orphan Drug and Fast Track designation for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

Assuming development efforts are successful for OrbeShield™, we believe potential government procurement contract(s) could reach as much as \$450 million.

### About GI ARS

ARS occurs after toxic radiation exposure and involves several organ systems, notably the bone marrow the GI tract and later the lungs. In the event of a nuclear disaster or terrorist detonation of a nuclear bomb, casualties exposed to >2 Gy are at high risk for development of clinically significant ARS. Exposure to high doses of radiation exceeding 10-12 Gy causes acute GI injury which can result in death in 5-15 days. The GI tract is highly sensitive due to the requirement for incessant proliferation of crypt stem cells and production of mucosal epithelium. The extent of injury to the bone marrow and the GI tract are the principal determinants of survival after exposure to TBI. Although the hematopoietic syndrome can be rescued by bone marrow transplantation or growth factor administration, there is no established treatment or preventive measure for the GI damage that occurs after high-dose radiation. Therefore, there is an urgent need to develop specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

### SGX943/SGX101– for Treating Melioidosis

SGX943 is the research name for the finished drug product, containing the active ingredient SGX94, which is being studied in melioidosis. A preliminary study with SGX943 has demonstrated efficacy. Further preclinical studies are planned with the pursuit of grant applications funding. Because SGX943 directly targets the innate immune system (and does not attempt to kill the bacteria directly), it is particularly relevant for antibiotic-resistant bacteria. The bacteria which causes melioidosis, *Burkholderia pseudomallei*, is known to be resistant to most antibiotics and to require prolonged treatment with the few antibiotics that do work. Thus, SGX943 may represent a much-needed novel and additive therapy for melioidosis.

SGX 101 is the research name for the human monoclonal antibody therapy for the treatment of melioidosis based upon Intrexon's advanced human antibody discovery, isolation, and production technologies.

### About Melioidosis

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

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

Australia and Northeast Thailand with increasing recognition of disease activity in coastal regions of India. Melioidosis has been under recognized and is likely to be under-reported in China.

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

#### The Drug Approval Process

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

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

An IND application is required before human clinical testing in the U.S. of a new drug compound or biological product can commence. The IND application includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

Clinical trials for INDs 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.



## Table of Contents

With certain exceptions, once positive 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. The FDA may also condition approval of a product on the sponsor agreeing to certain mitigation strategies that can limit the unfettered marketing of a drug. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes will likely be required to be submitted to the FDA or foreign regulatory authority.

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

For biodefense development, such as with RiVax™ and OrbeShield™, the FDA has instituted policies that are expected to result in shorter pathways to market. This potentially includes approval for commercial use utilizing the results of animal efficacy trials, rather than efficacy trials in humans. However, we will still have to establish that the vaccine and countermeasures 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 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 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.

Vaccines are approved under the Biologics Licensing Application ("BLA") process that exists under the Public Health Service Act (the "PHSA"). In addition to the greater technical challenges associated with developing biologics, the

potential for generic competition is much less for a BLA product than a small molecule product subject to an NDA under the Federal Food, Drug, and Cosmetic Act. Under the Patient Protection and Affordable Care Act enacted in 2010, a “generic” version of a biologic is known as a biosimilar and the barriers to entry – whether legal, scientific, or logistical – for a biosimilar version of a biologic approved under a BLA are much greater. Indeed, almost three years after the enactment of the Patient Protection and Affordable Care Act, no biosimilar application has even been filed with the FDA.

#### Marketing Strategies

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

## Table of Contents

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

We have had and are having strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of our biodefense vaccine products. We may market our biodefense vaccine products directly to government agencies. We believe that both military and civilian health authorities of the U.S. and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

## Competition

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

### SGX94/942 Competition

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

There is currently one drug approved for the treatment of oral mucositis in hematological cancer only (palifermin). There are currently no approved drugs for treatment of oral mucositis in cancers with solid tumors (e.g., head and neck cancer). There are at least five drugs in clinical development for oral mucositis – one in phase 3 (under development by Daewoong Pharmaceutical Co., Ltd), three in phase 2 (under development by ActoGenix N.V., BioAlliance Pharma S.A. and Alder Biopharmaceuticals Inc.) and one in phase 1 (under development by PolyMedix, Inc.). In addition, there are medical devices approved for the treatment of oral mucositis including MuGard, GelClair, Episil and Caphosol. These devices attempt to create a protective barrier around the oral ulceration; however, none of these devices are biologically based.

### Oral BDP Competition

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

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



## Table of Contents

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

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

### ThermoVax™ Competition

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

The majority of stabilization technologies currently being developed involve mixing vaccine antigen +/- adjuvant with various proprietary excipients or co-factors that either serve to stabilize the vaccine or biological product in a liquid or dried (lyophilized) form. Examples of these approaches include the use of various plant-derived sugars and macromolecules being developed by companies such as Stabilitech and synthetic polymers such as Pluronic F127 (Endo Pharmaceuticals under Gates Foundation funding). VBI (Variation Biotechnologies, Inc) intends to employ a lipid system (resembling liposomes) to stabilize viral antigens, including virus-like particles (VLPs), and apply it to a conventional influenza vaccine among others.

Other approaches involve process variations to freeze-dry live virus vaccines. For example, PaxVax intends to employ a spray drying technology in concert with enteric coating to achieve formulations for room temperature stability of live virus vaccines using adenovirus vectors. VBI has the capacity to utilize their proprietary stabilization technology for a number of vaccines (as a co-development service, similar to the business model being developed by Stabilitech), whereas PaxVax is applying the technology to their own proprietary vaccine development programs. Stabilitech uses combinations of excipients, which include glassifying sugars similar to the ThermoVax™ technology, and variations in drying cycles during lyophilization, as does the ThermoVax™ technology. Another Soligenix competitor, Endo Pharmaceuticals, is working to identify Pluronic polymer-based formulations that stabilize measles and hepatitis B vaccines from -10°C to 45°C.

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

### Vaccines/BioDefense Competition

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

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

agencies like the Institute of Medicine to recommend adoption of newer and safer anthrax vaccines. BioThrax® is FDA approved for the prevention of anthrax infection, but requires five doses over a period of 18 months to achieve protective immunity.

## Table of Contents

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

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

The only potential competition to RiVax™ is being developed by the U.S. Army Medical Research Institute of Infectious Diseases, the DoD's lead laboratory for medical research to counter biological threats. Development of this product, known as RVEc™, is proceeding under a program led by Dr. Len Smith, who has been working for many years to develop a ricin vaccine candidate. Similar to RiVax™, RVEc™ has been shown to be fully protective in mice exposed to lethal doses of ricin toxin by the aerosol route. Further studies, in both rabbits and nonhuman primates, were conducted to evaluate RVEc™'s safety as well as its immunogenicity, with positive results observed.

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

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

## Patents and Other Proprietary Rights

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

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

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



## Table of Contents

The subject of U.S. patent application number 12/633,631 filed December 8, 2009 and corresponding European patent application number 09836727.9 is the use of topically active BDP in radiation and chemotherapeutics injury.

Recently, we have expanded our patent portfolio to include innate defense regulation through the acquisition of the novel drug technology, known as SGX94. By binding to the pivotal regulatory protein p62, also known as sequestosome-1, SGX94 regulates the innate immune system to reduce inflammation, eliminate infection and enhance healing. As part of the acquisition, we acquired all rights, including composition of matter patents for SGX94 as well as other analogs and crystal structures of SGX94 with its protein target p62, including U.S. patent 8,124,721 and additional pending applications.

In addition to issued and pending patents, we also have “Orphan Drug” designations for SGX203 in the U.S. for pediatric Crohn’s disease, OrbeShield™ in the U.S. for GI ARS, orBec® in the U.S. and Europe (E.U.) for GI GVHD, as well as for RiVax™ in the U.S. Our Orphan Drug designations provide for seven years of post approval marketing exclusivity in the U.S. and ten years exclusivity in Europe. We have pending patent applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the U.S. seven year or E.U. 10 year post-approval exclusivity provided by Orphan Drug legislation.

### Oral BDP License Agreement

On November 24, 1998, our company, known at the time as Enteron Pharmaceuticals, Inc. (“Enteron”) and George B. McDonald (“Dr. McDonald”) entered into an exclusive license agreement for the rights to intellectual property, including know-how, relating to orBec®/oral BDP. We have an exclusive license to commercially exploit the covered products worldwide, subject to Dr. McDonald’s right to make and use the technology for research purposes and the U.S. Government’s right to use the technology for government purposes. In consideration for the license, we paid to Dr. McDonald a license fee in the amount of \$20,000 and are required to (i) reimburse Dr. McDonald for certain out-of-pocket expenses incurred by Dr. McDonald in connection with the patent applications and issued patents, (ii) pay Dr. McDonald a milestone payment in the amount of \$300,000, (iii) issue Dr. McDonald shares of common stock equal to 8% of our outstanding common stock as of November 24, 1998, with certain anti-dilution protection, and (iv) pay Dr. McDonald royalty payments equal to 6% of net sales of the covered products.

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

The term of this agreement expires upon the expiration of the licensed patent applications or patents. After five years from the date of the agreement, Dr. McDonald has the right to terminate this agreement in its entirety or to terminate exclusivity under the agreement if we or our sublicensee has not commercialized or are not actively attempting to commercialize a covered product.

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

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

orBec® by the EMEA.

31

---

## Table of Contents

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

### SGX 94 License Agreements

On December 18, 2012, we announced the acquisition of a novel drug technology, known as SGX94, representing a novel approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to reduce inflammation, eliminate infection and enhance tissue healing by binding to the pivotal regulatory protein p62, also known as sequestosome-1. As part of the acquisition, we acquired all rights, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94. We also assumed a license agreement with UBC to advance the research and development of the SGX94 technology. The license agreement with UBC provides us with exclusive worldwide rights to manufacture, distribute, market sell and/or license or sublicense products derived or developed from this technology. Under the license agreement we are obligated to pay UBC (i) an annual license maintenance fee of CAN \$1,000, and (ii) milestone payments which could reach up to CAN \$1.2 million.

### ThermoVax™ License Agreement

On September 1, 2009, we executed a worldwide exclusive option to license patent applications with the UC for ThermoVax™ which is the subject of U.S. patent number 8,444,991 issued on May 22, 2013 titled “Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition.” This patent and its corresponding foreign filings are licensed to Soligenix by the UC and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement also covers thermostable vaccines for biodefense as well as other potential vaccine indications. In addition, Soligenix, in conjunction with UC, filed a patent application number 13/474,661 on May 17, 2012 titled: “Thermostable Vaccine Compositions and Methods of Preparing Same.”

### RiVax™ License Agreement

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

### VeloThrax™ License Option Agreement

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

### Intrexon Exclusive Channel Collaboration Agreement

On April 27, 2013, we entered into an exclusive channel collaboration agreement with Intrexon (the “Channel Agreement”) that governs an arrangement in which we intend to use Intrexon’s advanced human antibody discovery, isolation, and production technologies for the development of human monoclonal antibody therapies for a new biodefense application. The target of the channel collaboration will be melioidosis, a potentially lethal disease caused by the Gram-negative bacteria *Burkholderia pseudomallei*, which is endemic in Southeast Asia and Northern Australia.

The Channel Agreement grants us an exclusive worldwide license to use specified patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of products for the treatment of melioidosis through the use of exogenously produced human recombinant monoclonal antibodies.

In exchange for the license, we paid Intrexon a one-time technology access fee of \$1,500,000 in common stock. Additionally, the Channel Agreement requires us to make certain milestone payments to Intrexon which could reach up to \$7 million and to pay Intrexon royalty payments based upon sales of products based upon Intrexon’s technology.

#### Research and Development Expenditure

We spent approximately \$2.6 million and \$6.3 million in the years ended December 31, 2012 and 2011, respectively, on research and development. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations” beginning on page 34 of this prospectus for more information on the amounts we spent on research and development per product during the years ended December 31, 2012 and 2011, respectively.

Table of Contents

Employees

As of March 30, 2013, we had nine full-time employees, four of whom are MDs/PhDs.

Properties

We currently lease approximately 5,250 square feet of office space at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540. This office space currently serves as our corporate headquarters. On February 7, 2012, we entered into a lease agreement through March 31, 2015 for our existing office space. The rent for the first 12 months was approximately \$8,000 per month, or approximately \$18.25 per square foot on an annualized basis. This rent increased to approximately \$8,310 per month, or approximately \$19.00 per square foot on an annualized basis, for the remaining 24 months. Our office space is sufficient to satisfy our current needs.

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.

Table of Contents

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operations and financial condition. You should read this analysis in conjunction with our audited consolidated financial statements and related notes and our unaudited consolidated interim financial statements and their notes. This discussion and analysis 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 prospectus, which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Risk Factors" in this prospectus. See "Forward-Looking Statements."

Our Business Overview

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

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

An outline of our business strategy follows:

Complete a Phase 1 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn's disease;

Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;

Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic graft-versus-host disease ("GVHD");

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

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

Explore other business development and merger/acquisition strategies.

Critical Accounting Policies

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

## Table of Contents

### Intangible Assets

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

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

### Research and Development Costs

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

### Revenue Recognition

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



## Table of Contents

### Stock-Based Compensation

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

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

Stock compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted is amortized as the options vest.

### Results of Operations

#### Three Months Ended March 31, 2013 Compared to March 31, 2012

For the three months ended March 31, 2013, we had a net loss of \$1,087,414 as compared to a net loss of \$1,438,755 for same period in the prior year, representing a reduction in the net loss of \$351,341 or 24%.

For the three months ended March 31, 2013, revenues and associated costs relate to NIH grants awarded in support of our development of ricin and thermostable vaccines and oral BDP. For the three months ended March 31, 2013, we had revenues of \$900,354 as compared to \$647,418 for the same period in the prior year, representing an increase of \$252,936, or 39%. The increases in revenues were a result of increases in NIH grant revenues and the development work underlying them.

We incurred costs related to those revenues for the three months ended March 31, 2013 and 2012 of \$743,657 and \$556,571, respectively, representing an increase of \$187,086, or 34%. These costs relate to allocated employee costs and payments made to subcontractors in connection with research performed pursuant to the grants.

Our gross profit for the three months ended March 31, 2012 was \$156,697, as compared to \$90,847 for the same period in 2012, representing an increase of \$65,850, or 72%. The increase in gross profit follows directly from the increases in grant revenues discussed above.

Research and development spending decreased by \$120,141, or 14%, to \$756,653 for the three months ended March 31, 2013 as compared to \$876,794 for the same period in 2012. The decrease is due to a reduction in headcount and additional allocation of employee costs pursuant to grant awards.

General and administrative expenses decreased by \$167,102, or 26%, to \$487,941 for the three months ended March 31, 2013, as compared to \$655,043 for the same period in 2012. The decrease is due to a reduction in headcount and outside professional services.

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

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

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

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

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

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

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

## Table of Contents

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

During the year ended December 31, 2012, in accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused net operating loss ("NOL") carryforwards to other New Jersey-based corporate taxpayers based in New Jersey, we sold New Jersey NOL carryforwards, resulting in the recognition of \$521,458 of income tax benefit, net of transaction costs. There can be no assurance as to the continuation or magnitude of this program in future years.

## Business Segments

We maintain two active business segments for the year ended December 31, 2012 and December 31, 2011: Vaccines/BioDefense and BioTherapeutics.

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

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

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

## Financial Condition and Liquidity

### Cash and Working Capital

As of March 31, 2013, we had cash and cash equivalents of \$2,612,021 as compared to \$3,356,380 as of December 31, 2012, representing a decrease of \$744,359 or 22%. As of March 31, 2013, we had working capital of \$1,763,848 as compared to working capital of \$2,682,383 as of December 31, 2012, representing a decrease of \$918,535, or 34%.

## Table of Contents

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

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

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

We have approximately \$3.6 million in active grant funding still available to support our associated research programs in 2014. We plan to submit additional grant applications for further support of these programs with various funding agencies.

We have continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expect to continue to do so for the foreseeable future.

We will pursue NOL sales in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$521,458 in proceeds from the sale of NJ NOL in 2012, we expect to participate in this program during 2013 and beyond as the program is available; and

We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

### Reverse Stock Split

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

### Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately \$3.4 million before any grant reimbursements, of which \$0.6 million relates to the BioTherapeutics business and \$2.8 million relates to the Vaccines/BioDefense business. We anticipate grant revenues in the next 12 months of approximately \$3.1 million to offset research and development expenses, primarily for the development of our ThermoVax™ vaccine technology.

Table of Contents

The table below details our costs for research and development by program and amounts reimbursed for the three months ended March 31, 2013 compared to March 31, 2012:

	2013	2012
<b>Research &amp; Development Expenses</b>		
Oral BDP	\$ 275,066	\$ 360,070
RiVax™ and ThermoVax™ Vaccines	398,641	458,174
SGX 94	50,789	-
Other	32,157	58,550
<b>Total</b>	<b>\$ 756,653</b>	<b>\$ 876,794</b>
<b>Reimbursed under NIH Grants</b>		
Oral BDP	\$ 63,619	\$ 49,813
RiVax™ and thermostable vaccines	680,038	506,758
<b>Total</b>	<b>\$ 743,657</b>	<b>\$ 556,571</b>
<b>Grand Total</b>	<b>\$ 1,500,310</b>	<b>\$ 1,433,365</b>

**Contractual Obligations**

We have commitments of approximately \$368,800 as of March 31, 2013 relating to several licensing agreements with consultants and universities, which upon clinical or commercialization may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization milestones will occur.

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

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey immediately prior to completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from us and/or our stockholders to a third party: 50,000 common shares to Dr. Schaber; and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes our obligation to issue shares if such event occurs.

Employees with employment contracts have severance agreements that will provide separation benefits from our company if they are involuntarily separated from employment. On February 15, 2012, our employment agreement with our former Chief Financial Officer of the company was terminated.

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

Year	Research and Development	Property and Other Leases	Total
2013	\$ 43,800	\$ 79,100	\$ 122,900
2014	100,000	101,200	201,200
2015	75,000	25,000	100,000

Edgar Filing: SOLIGENIX, INC. - Form S-1/A

2016	75,000	-	75,000
2017	75,000	-	75,000
Total	\$ 368,800	\$ 205,300	\$ 574,100

Table of Contents

## MANAGEMENT

The table below contains information as of the date of this prospectus regarding the current members of the Board of Directors and executive officers.

Name	Age	Position
Christopher J. Schaber, PhD	46	Chairman of the Board, Chief Executive Officer and President
Keith L. Brownlie, CPA	60	Director
Gregg A. Lapointe, CPA	54	Director
Robert J. Rubin, MD	67	Director
Jerome Zeldis, MD, PhD	63	Director
Robert N. Brey, PhD	62	Chief Scientific Officer and Senior Vice President
Kevin J. Horgan, MD	53	Chief Medical Officer and Senior Vice President
Joseph M. Warusz, CPA	57	Vice President of Finance, Acting Chief Financial Officer and Corporate Secretary

Christopher J. Schaber, PhD has over 23 years of experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been our President and Chief Executive Officer and a director since August 2006. He was appointed Chairman of the Board on October 8, 2009. He also serves on the board of directors of the Biotechnology Council of New Jersey (“BioNJ”) since January 2009, and is a member of the corporate councils of both the National Organization for Rare Diseases (“NORD”) and the American Society for Blood and Marrow Transplantation (“ASBMT”) since October 2009 and July 2009, respectively. Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, pre-clinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. During his tenure at Discovery Laboratories, Inc., Dr. Schaber played a significant role in raising over \$150 million through both public offerings and private placements. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his BA degree from Western Maryland College, his MS degree in Pharmaceutics from Temple University School of Pharmacy and his PhD degree in Pharmaceutical Sciences from the Union Graduate School. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as an executive senior officer with our company and Discovery Laboratories, Inc., and as a member of the board of directors of BioNJ; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

Keith L. Brownlie, CPA has been a director since June 2011. Mr. Brownlie currently serves as a member of the Board of Directors of Epicept Corporation, a publicly traded, specialty pharmaceutical company focused on the clinical development and commercialization of pharmaceutical products for the treatment of cancer and pain, a position he has held since April 2011. Mr. Brownlie also serves on the Board of Directors of RXi Pharmaceuticals Corporation, a publicly traded biotechnology company involved in the research and development of RNAi products for the diagnosis, prevention and treatment of human diseases, a position he has held since June 2012. From 1974 to 2010, Mr. Brownlie worked with the accounting firm of Ernst & Young LLP where he served as audit partner for numerous public companies and was the Life Sciences Industry Leader for the New York metro area where he was involved with over 100 public and private financings and M&A transactions. Mr. Brownlie received a BS in Accounting from Lehigh

University and is a Certified Public Accountant in the state of New Jersey. Mr. Brownlie co-founded the New Jersey Entrepreneur of the Year Program and was Vice President and Trustee of the New Jersey Society of CPAs. In addition, he served as accounting advisor to the board of the Biotechnology Council of New Jersey. Mr. Brownlie was selected to serve as a member of our Board of Directors because of his vast experience as an audit partner for numerous public companies and as a director of a publicly traded specialty pharmaceutical and biotechnology companies.



Table of Contents

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

Robert J. Rubin, MD has been a director since October 2009. Dr. Rubin was a clinical professor of medicine at Georgetown University from 1995 until 2012 when he was appointed a Distinguished Professor of Medicine. From 1987 to 2001, he was president of the Lewin Group (purchased by Quintiles Transnational Corp. in 1996), an international health policy and management consulting firm. From 1994 to 1996, Dr. Rubin served as Medical Director of ValueRx, a pharmaceutical benefits company. From 1992 to 1996, Dr. Rubin served as President of Lewin-VHI, a health care consulting company. From 1987 to 1992, he served as President of Lewin-ICF, a health care consulting company. From 1984 to 1987, Dr. Rubin served as a principal of ICF, Inc., a health care consulting company. From 1981 to 1984, Dr. Rubin served as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services and as the Assistant Surgeon General in the U.S. Public Health Service. Dr. Rubin has served on the Board of CardioNet, Inc. since 2007. He is a board certified nephrologist and internist. Dr. Rubin received an undergraduate degree in Political Science from Williams College and his medical degree from Cornell University Medical College. Dr. Rubin was selected to serve as a member of our Board of Directors because of his vast experience in the health care industry, including his experience as a nephrologist, internist, clinical professor of medicine and Assistant Surgeon General, and his business experience in the pharmaceutical industry.

Jerome Zeldis, MD, PhD has been a director since June 2011. Dr. Zeldis is currently Chief Executive Officer of Celgene Global Health and Chief Medical Officer of Celgene Corporation, a publicly traded, fully integrated biopharmaceutical company, where he has been employed since 1997. From September 1994 to February 1997, Dr. Zeldis worked at Sandoz Research Institute and the Janssen Research Institute in both clinical research and medical development. He has been a board member of several biotechnology companies and is currently on the boards of the NJ Chapter of the Arthritis Foundation, the Castleman’s Disease Organization and PTC Therapeutics. Additionally, he has served as Assistant Professor of Medicine at the Harvard Medical School (from July 1987 to September 1988), Associate Professor of Medicine at University of California, Davis from (September 1988 to September 1994), Clinical Associate Professor of Medicine at Cornell Medical School (January 1995 to December 2003) and Professor of Clinical Medicine at the Robert Wood Johnson Medical School (July 1998 to June 2010). Dr. Zeldis received a BA and an MS from Brown University, and an M Phil, an MD, and a PhD in Molecular Biophysics and Biochemistry from Yale University. Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and in Gastroenterology at the Massachusetts General Hospital and Harvard Medical School. He has published 116 peer reviewed articles and 24 reviews, book chapters, and editorials. Dr. Zeldis was selected to serve as a member of our Board of Directors because of his experience as an executive officer of a publicly traded biopharmaceutical company and in clinical research and medical development, and his experience in the health care industry, including his experience as an internist, gastroenterologist and professor of medicine.



## Table of Contents

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

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

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

## Board Leadership Structure and Independence

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

employees, and collaborative partners.

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

## Table of Contents

Although we believe 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 our Board of Directors may determine that it is more appropriate to separate the roles in the future.

### Code of Ethics

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

### Diversity Considerations in Identifying Director Nominees

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

### Audit Committee Financial Expert

We have an audit committee comprised of Messrs. Brownlie (Chair) and Lapointe and Dr. Rubin. Our Board of Directors has determined that Mr. Brownlie qualifies as an “audit committee financial expert,” as defined under the rules of the Securities and Exchange Commission. Our Board of Directors has also determined that the members of our Audit Committee are qualified to serve on the committee and have the experience and knowledge to perform the duties required of the committee.

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

Table of Contents

## EXECUTIVE COMPENSATION

## Summary Compensation

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

## Summary Compensation

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

<sup>1</sup>Dr. Schaber deferred payment of his 2011 annual bonus of \$50,000 until January 15, 2012. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us. In 2012, no bonus was awarded or option awards issued.

<sup>2</sup>Dr. Brey deferred payment of his 2011 annual bonus of \$13,000 until January 15, 2012. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us. In 2012, no bonus was awarded or option awards issued.

<sup>3</sup>Dr. Horgan deferred payment of his 2011 annual bonus of \$13,000 until January 15, 2012. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us. In 2012, no bonus was awarded or option awards issued.

<sup>4</sup>Mr. Warusz deferred payment of his 2011 annual bonus of \$7,000 until January 15, 2012. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us. In 2012, no bonus was awarded or option awards issued.

## Employment and Severance Agreements

In August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, PhD. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of \$300,000 per year and a minimum annual bonus of \$100,000. This employment agreement was renewed in December 27, 2007 for an additional term of three years. We agreed to issue him options to purchase 125,000 shares of our common stock, with one third immediately

vesting and the remainder vesting over three years. Upon termination without “Just Cause” as defined by this agreement, we would pay Dr. Schaber nine months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependents. No unvested options shall vest beyond the termination date. Dr. Schaber’s monetary compensation (base salary of \$300,000 and bonus of \$100,000) remained unchanged from 2006 with the 2007 renewal. Upon a change in control of our company due to merger or acquisition, all of Dr. Schaber’s options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during the term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber’s immediate family. This agreement automatically renewed in December 2010 for an additional term of three years.

Table of Contents

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

In January 2011, we entered into a two-year employment agreement with Dr. Kevin J. Horgan. Pursuant to this employment agreement we agreed to pay Dr. Horgan a base salary of \$290,000 per year, a one-time signing bonus of \$15,000 and a targeted annual bonus of 30% of base salary. We agreed to issue him options to purchase 62,500 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Horgan six months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance benefits for Dr. Horgan and his dependants. No unvested options shall vest beyond the termination date. On December 6, 2012, the Compensation Committee approved the increase in salary for Dr. Horgan to \$300,000.

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

In May 2011, we entered into a one-year employment agreement with Mr. Joseph M. Warusz, our Acting Chief Financial Officer, Vice President Finance and Chief Accounting Officer. Pursuant to the agreement, we have agreed to pay Mr. Warusz \$175,000 per year and a targeted annual bonus of 20% of base salary. We also agreed to issue him options to purchase 40,000 shares of our common stock with one-third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause", as defined in this agreement, we would pay Mr. Warusz three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 1, 2011, the Compensation Committee increased the salary of Mr. Warusz to \$180,000. On December 6, 2012, the Compensation Committee approved the increase in salary for Mr. Warusz to \$186,000.

In February 2007, our Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from our company and/or our stockholders to a third party: 50,000 common shares to Dr. Schaber and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes our obligation to issue such shares to him if such event occurs.



Table of Contents

## Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2012. We have never issued Stock Appreciation Rights.

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

## Outstanding Equity Awards at Fiscal Year-End

## Compensation of Directors

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

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

---

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

Table of Contents

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

3Ms. Howson and Mr. Thompson did not stand for re-election to the Board of Directors at our June 21, 2012 Annual Meeting of Stockholders.

Stock Ownership Policy

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

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

Table of Contents

## SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT

The table below provides information regarding the beneficial ownership of the common stock as of the date of this prospectus, 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 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 the date of this prospectus 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 12,231,492 shares of common stock outstanding as of the date of this prospectus.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Class
Paolo Cavazza (1)	3,379,950	26.66%
Sigma-Tau Pharmaceuticals, Inc. (2)	3,068,461	24.37%
Intrexon Corporation (3)	1,034,483	8.46%
Christopher J. Schaber (4)	547,134	4.30%
Gregg A. Lapointe (5)	138,886	*
Robert N. Brey (6)	142,187	*
Robert J. Rubin (7)	76,599	*
Joseph Warusz (8)	48,750	*
Kevin J. Horgan (9)	92,185	*
Keith Brownlie (10)	40,000	*
Jerry Zeldis (11)	40,000	*
All directors and executive officers as a group (8 persons)	1,125,741	8.50%

1Includes (a) 2,711,392 shares of common stock and warrants to purchase 357,069 shares of common stock exercisable within 60 days of the date of this prospectus held by Sigma-Tau Pharmaceuticals, Inc., (b) 164,146 shares of common stock and warrants to purchase 87,854 shares held by SINAF SA, and (c) 59,539 shares held by Mr. Paolo Cavazza. Sigma-Tau Pharmaceuticals, Inc. is a direct wholly-owned subsidiary of Sigma-Tau America S.A., which is a direct wholly-owned subsidiary of Sigma-Tau International S.A., which is a direct wholly-owned subsidiary of Sigma-Tau Finanziaria S.p.A. Mr. Paolo Cavazza directly and indirectly owns 38% of Sigma-Tau Finanziaria S.p.A. SINAF SA is an indirect wholly owned subsidiary of Aptafin S.p.A., which is owned by Mr. Paolo Cavazza and members of his family. Accordingly, Mr. Paolo Cavazza may be deemed to beneficially own the shares beneficially owned by Sigma-Tau Pharmaceuticals, Inc. and Chaumiere Sarl. Mr. Paolo Cavazza's address is Via Tesserte, 10, Lugano, Switzerland.

2Includes 2,711,392 shares of common stock and warrants to purchase 357,069 shares of common stock exercisable within 60 days of the date of this prospectus. The amount does not include 59,539 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.

<sup>3</sup>Includes 1,034,483 shares of common stock. The address of Intrexon Corporation is 20358 Seneca Meadows Parkway, Germantown, MD 20876.

Table of Contents

- 4 Includes 50,158 shares of common stock owned by Dr. Schaber, options to purchase 495,000 shares of common stock exercisable within 60 days of the date of this prospectus, and warrants to purchase 1,976 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 .
- 5 Includes 48,781 shares of common stock, options to purchase 60,837 shares of common stock exercisable within 60 days of the date of this prospectus, and warrants to purchase 29,268 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 .
- 6 Includes options to purchase 142,187 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Brey is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 .
- 7 Includes 12,195 shares of common stock, options to purchase 57,087 shares of common stock exercisable within 60 days of the date of this prospectus, and warrants to purchase 7,317 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 8 Includes options to purchase 48,750 shares of common stock owned by Mr. Warusz exercisable within 60 days of the date of this prospectus. The address of Mr. Warusz is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 9 Includes options to purchase 92,185 shares of common stock owned by Dr. Horgan exercisable within 60 days of the date of this prospectus. The address of Dr. Horgan is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 10 Includes options to purchase 40,000 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Mr. Brownlie is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- 11 Includes options to purchase 40,000 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Mr. Zeldis is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

\*Indicates less than 1%.

Table of Contents

## 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 500,000 shares, bringing the total shares reserved for issuance under the plan to 1,000,000 shares. In September 2010, our stockholders approved a second amendment to the 2005 Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under the plan by 750,000 shares, bringing the total shares reserved for issuance under the plan to 1,750,000 shares. The following table provides information, as of December 31, 2012 with respect to options outstanding under our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders (1)	1,457,724	\$ 3.19	129,711
Equity compensation plans not approved by security holders	-	-	-
Total	1,457,724	\$ 3.19	129,711

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.

**TRANSACTIONS WITH RELATED  
PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS**

## Related Party Transactions

Other than the employment agreements and compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2011.

## Director Independence

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

Table of Contents

PLAN OF DISTRIBUTION

We are offering up to 5,405,405 units on a “best efforts” basis for aggregate gross proceeds of up to \$10 million and for \$\_\_\_\_ per unit, to be issued in one or more closings, each consisting of (i) one share of common stock, (ii) a warrant to purchase an additional 0.75 share of common stock and (iii) a preferred stock purchase right in accordance with the Rights Agreement, dated June 22, 2007, between us and American Stock Transfer & Trust Company. There can be no assurance that the offering will be fully subscribed. Accordingly, we may sell substantially less than \$10 million of our units, in which case our gross proceeds would be substantially reduced.

We reserve the right, in our sole discretion and without prior notice to other investors, to offer certain investors in the offering additional rights and preferences, including, without limitation, board nomination rights. We will not, however, offer investors different pricing terms for the securities offered hereby.

Maxim Group LLC is acting as our lead managing placement agent for this offering. The placement agent is not purchasing or selling any units, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of units, other than to use its “best efforts” to arrange for the sale of units by us. Therefore, we may not sell the entire amount of units being offered. Additionally, we and the placement agent may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.

Upon the declaration of effectiveness of the registration statement of which this prospectus is a part, we will enter into a placement agency agreement with the placement agent. The terms of the placement agency agreement to provide that the obligations of the placement agent are subject to certain conditions precedent, including the absence of any material adverse change in our business and the receipt of certain certificates, opinions and letters from us, our counsel and our auditors. The placement agency agreement will not give rise to any commitment by the placement agent to purchase any of our shares of common stock, and the placement agent will have no authority to bind us by virtue of the placement agency agreement. We will also enter into separate securities purchase agreements with each investor in this offering.

Pursuant to an escrow agreement among us, the placement agent and U.S. Bank, N.A., as escrow agent, the funds received in payment for the shares of common stock and warrants sold in this offering will be wired to a non-interest bearing escrow account and held until we and the placement agent notify the escrow agent that this offering has closed, indicating the date on which the shares of common stock and warrants are to be delivered to the purchasers and the net proceeds are to be delivered to us. Unless investors instruct us otherwise, we will deliver the shares of common stock being issued to the investors electronically. In addition, at the closing of this offering, we will issue such purchasers warrant certificates for the warrants being issued as part of the units offered hereby.

Pursuant to the placement agency agreement, upon the completion of all closings of the offering, we will pay the placement agent a cash fee equal to (i) 8% of the gross proceeds received by investors who purchase units in the offering that are contacted by the placement agent and (ii) 4% of the gross proceeds received from our officers or directors (in excess of the first \$300,000 of gross proceeds received from such officers and directors) or from certain investors with which we have a previous relationship. In addition, we agreed to grant the placement agent warrants to purchase a number of shares of our common stock equal to 5% of the number of units sold by us in the offering (excluding shares sold to our officers and directors). The placement agent warrants will have substantially the same terms as the warrants issued to the public in the offering (except they will provide for a “cashless exercise” feature) and will be subject to FINRA Rule 5110(g)(1) in that for a period of 180 days following the effectiveness of the registration statement (which shall not be earlier than the closing date of the offering pursuant to which the placement agent warrants are being issued), neither the placement agent warrants nor any warrant shares issued upon exercise of the placement agent warrants shall be (A) sold, transferred, assigned, pledged, or hypothecated, or (B) the subject of



any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness of the registration statement pursuant to which the placement agent warrants are being issued, except the transfer of any security as permitted by FINRA rules. Upon engagement of the placement agent, we paid to Maxim Group LLC a cash retainer of \$25,000 as a refundable advance to be applied towards out-of-pocket expenses incurred. In addition, we will reimburse the lead managing placement agent for its out-of-pocket expenses, including, without limitation fees and expenses of the lead managing placement agent's legal counsel, travel, lodging and other expenses up to a maximum of \$100,000 in the aggregate (which \$25,000 advance is included in the \$100,000 maximum), provided, however, that any expense over \$5,000 shall be approved in writing by us. Further, we are responsible for paying all costs associated with I-Deal and roadshows (up to a maximum of \$25,000) and any out-of-pocket expenses incurred in relation to the I-Deal and roadshows (which such expenses are included in the \$100,000 aggregate referred to above). In addition, the placement agent shall be responsible for any fees in connection with conducting background checks on our officers and directors.

Table of Contents

The placement agent may be deemed to be underwriters within the meaning of Section 2(a)(11) of the Securities Act and any commissions received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants to purchase shares of common stock by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

The placement agency agreement provides that we will indemnify the placement agent and any other broker or dealers which the placement agent may engage to act as sub-agents or select dealers on the placement agent's behalf in connection with the offering against specified liabilities, including liabilities under the Securities Act. We have been advised that, in the opinion of the Securities and Exchange Commission, indemnification for liabilities under the Securities Act is against public policy as expressed in the Securities Act and is therefore unenforceable.

Pursuant to the placement agency agreement, our officers and directors will be prohibited from selling or transferring any of our securities for a period ending on the 9-month anniversary of the date of this prospectus. Each of such persons has agreed to execute a "lock-up" agreement with the placement agent regarding such restrictions. This means that, subject to certain exceptions, for the applicable lock-up period following the date of this prospectus, our officers and directors may not, directly or indirectly, offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of any shares of our common stock, without the prior written consent of Maxim Group LLC. At any time and without public notice, Maxim Group LLC may, in its sole discretion, release all or some of the securities from these lock-up agreements.

Table of Contents

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 50,350,000 shares of capital stock, of which 50,000,000 shares are common stock, par value \$0.001 per share, 230,000 shares are preferred stock, 10,000 shares are Series B Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding), 10,000 shares are Series C Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding) and 100,000 shares are Series A Junior Participating Preferred Stock, par value \$0.001 per share (which are available for issuance under our shareholder rights plan). As of the date of this prospectus, there were issued and outstanding 12,231,492 shares of common stock, options to purchase 1,446,474 shares of common stock and warrants to purchase 2,843,338 shares of common stock. The amount outstanding does not include the 5,405,405 shares of common stock or the 4,054,054 shares of common stock underlying to warrants to be included in the 5,405,405 units.

Common Stock

Holders of our common stock are entitled to one vote for each share held in the election of directors and in all other matters to be voted on by the stockholders. There is no cumulative voting in the election of directors. Holders of common stock are entitled to receive dividends as may be declared from time to time by our board of directors out of funds legally available therefor. In the event of liquidation, dissolution or winding up of the corporation, holders of common stock are to share in all assets remaining after the payment of liabilities. Holders of common stock have no pre-emptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the common stock. The rights of the holders of the common stock are subject to any rights that may be fixed for holders of preferred stock. All of the outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 230,000 shares of preferred stock, 10,000 shares of Series B Convertible Preferred Stock, par value \$0.05 per share ("Series B Preferred Stock"), 10,000 shares of Series C Convertible Preferred Stock, par value \$0.05 per share ("Series C Preferred Stock"), and 100,000 shares of Series A Junior Participating Preferred Stock, par value \$0.001 per share ("Junior Preferred Stock"). The board of directors is empowered, without stockholder approval, to designate and issue additional series of preferred stock with dividend, liquidation, conversion, voting or other rights, including the right to issue convertible securities with no limitations on conversion, which could adversely affect the voting power or other rights of the holders of our common stock, substantially dilute a common stockholder's interest and depress the price of our common stock.

No shares of the Series B Preferred Stock, the Series C Preferred Stock or the Junior Preferred Stock are outstanding. Due to the terms of the Series C Preferred Stock, no additional shares of Series C Preferred Stock can be issued.

Series B Preferred Stock

Our Board of Directors has authorized the issuance of 10,000 shares of Series B Preferred Stock, 6,411 of which have been converted to common stock and therefore are not reissuable.

Voting

Each holder of Series B Preferred Stock is entitled to the number of votes equal to the number of whole shares of common stock into which the shares of Series Preferred Stock held by such holder is then convertible (as adjusted from time to time pursuant to the Certificate of Incorporation) with respect to any and all matters presented to the

stockholders for their action or consideration. Except as provided by law, holders of Series B Preferred Stock vote together with the holders of common stock as a single class.

#### Dividends

The holders of the Series B Preferred Stock are entitled to a dividend of 8% per annum, payable annually in shares of Series B Preferred Stock. In addition, when and if the Board of Directors shall declare a dividend payable with respect to the then outstanding shares of common stock, the holders of the Series B Preferred Stock are entitled to the amount of dividends per share as would be payable on the largest number of whole shares of common stock into which each share of Series B Preferred Stock could then be converted.

## Table of Contents

### Conversion

Each share of Series B Cumulative Convertible Preferred are convertible into 13.33 shares of common stock. The conversion ratio is subject to an adjustment upon the issuance of additional shares of common stock for a price below the closing price of the common stock and equitable adjustment for stock splits, dividends, combinations, reorganizations and similar events.

### Liquidation

In the event of liquidation, dissolution or winding up of the company, the holders of Series B Preferred Stock then outstanding will be entitled to be paid an amount equal to \$100 per share (subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares pursuant to the Certificate of Incorporation), plus any dividends declared but unpaid thereon before any payment is made to the holders of common stock, Junior Preferred Stock or any other class or series of stock ranking on liquidation junior to the Series B Preferred Stock. After the holders of the Series B Preferred Stock have been paid in full, the remaining assets of the company will be distributed to the holders of Junior Preferred Stock and common stock, subject to the preferences of the Junior Preferred Stock.

### Redemption

Subject to certain conditions, after the second anniversary of the issuance of the Series B Preferred Stock, the company will have the right, but not the obligation, to redeem the then-outstanding shares of Series B Preferred Stock for cash in an amount calculated pursuant to the terms of the Certificate of Incorporation.

### Junior Preferred Stock

#### Voting

The holders of the Junior Preferred Stock will have 1,000 votes per share of Junior Preferred Stock on all matters submitted to a vote of our stockholders, including the election of directors.

#### Dividends

If the Board of Directors declares or pays dividends on common stock, the holders of the Junior Preferred Stock would be entitled to receive a per share dividend payment of 1,000 times the dividend declared per share of common stock. In the event we make a distribution on the common stock, the holders of the Junior Preferred Stock will be entitled to a per share distribution, in like kind, of 1,000 times such distribution made per share of common stock. In the event of any merger, consolidation or other transaction in which shares of common stock are exchanged, each share of Junior Preferred Stock will be entitled to receive 1,000 times the amount received per share of common stock. These rights are protected by customary anti-dilution provisions.

#### Liquidation

Upon any liquidation, dissolution or winding up, no distribution may be made to the holders of shares of stock ranking junior to the Junior Preferred Stock unless the holders of the Junior Preferred Stock have received the greater of (i) \$3.70 per one one-thousandth share plus an amount equal to accrued and unpaid dividends and distributions thereon, and (ii) an amount equal to 1,000 times the aggregate amount to be distributed per share to holders of common stock. Further, no distribution may be made to the holders of stock ranking on a parity upon liquidation, dissolution or winding up with the Junior Preferred Stock, unless distributions are made ratably on the Junior Preferred Stock and all

other shares of such parity stock in proportion to the total amounts to which the holders of the Junior Preferred Stock are entitled above and to which the holders of such parity shares are entitled.

## Table of Contents

### Shareholder Rights Plan

On June 22, 2007, our board of directors adopted a shareholder rights plan for our company and in connection therewith declared a dividend of one preferred share purchase right for each outstanding share of common stock. Each Right entitles the registered holder to purchase one one-thousandth of a share of our Junior Preferred Stock at a price of \$3.70 per one one-thousandth of a share, subject to certain adjustments. Initially, the rights are not exercisable, but become exercisable upon the earlier of (i) 10 days following a public announcement that a person or group of affiliated or associated persons, with certain exceptions, has acquired beneficial ownership of 15% or more of the then outstanding common stock or (ii) 10 business days following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of such outstanding common stock.

Our board may redeem all of the rights for \$0.001 per right at any time before the earlier of (i) the time the rights become exercisable or (ii) July 1, 2017, the date the rights expire.

### Anti-Takeover Provisions

Provisions in our Certificate of Incorporation, by-laws and stockholder rights plan may discourage certain types of transactions involving an actual or potential change of control of our company which might be beneficial to us or our security holders.

As noted above, our Certificate of Incorporation permits our board of directors to issue shares of any class or series of preferred stock in the future without stockholder approval and upon such terms as our board of directors may determine. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any class or series of preferred stock that may be issued in the future.

Our bylaws generally provide that any board vacancy, including a vacancy resulting from an increase in the authorized number of directors, may be filled by a majority of the directors, even if less than a quorum.

Additionally, our bylaws provide that stockholders must provide timely notice in writing to bring business before an annual meeting of shareholders or to nominate candidates for election as directors at an annual meeting of shareholders. Notice for an annual meeting is timely if our Secretary receives the written notice not less than 45 days and no more than 75 days prior to the anniversary of the date that we mailed proxy materials for the preceding year's annual meeting. However, if the date of the annual meeting is advanced more than thirty (30) days prior to, or delayed by more than thirty (30) days after, the anniversary of the preceding year's annual meeting, notice by the stockholder to be timely must be delivered not later than the close of business on the later of (i) the 90th day prior to such annual meeting or (ii) the 10th day following the day on which public announcement of the date of such annual meeting is first made. Our bylaws also specify the form and content of a shareholder's notice. These provisions may prevent shareholders from bringing matters before an annual meeting of shareholders or from making nominations for directors at an annual meeting of shareholders.

### Warrants

As of the date of this prospectus, warrants for the issuance of 2,843,338 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of \$3.13 per share.

### Unit Warrants and Placement Agent Warrants

In connection with this offering, we may issue warrants to purchase up to 4,054,054 shares of common stock. The warrants entitle holders to purchase 0.75 share of our common stock for each warrant they hold at a price equal to \_\_\_\_\_% of the price of each unit. After the expiration of the exercise period, unit warrant holders will have no further rights to exercise such unit warrants.

The unit warrants may be exercised only for full shares of common stock, and may be exercised on a “cashless” basis. If the registration statement covering the shares issuable upon exercise of the warrants contained in the units is no longer effective, the unit warrants may only be exercised on a “cashless” basis and will be issued with restrictive legends unless such shares are eligible for sale under Rule 144. We will not issue fractional shares of common stock. As to any fraction of a share which the unit warrant holder would otherwise be entitled to purchase upon exercise, we will, at our election, either pay a cash adjustment in respect of such fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole share.

Unit warrant holders do not have any voting or other rights as a stockholder of our company. The exercise price and the number of shares of common stock purchasable upon the exercise of each unit warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

Certain institutional investors may be prohibited, pursuant to their investment charter or other governing documents, from acquiring warrants. Accordingly, we and the placement agent may, upon request of any such investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants will be at the same offering price per unit as all other investors.

We may issue placement agent warrants to the placement agent to purchase up to 270,271 shares of common stock that will be issuable upon exercise of the placement agent warrants at an exercise price of \$\_\_\_\_\_ per share, assuming all of the units are sold in this offering and that none of our officers and directors purchase units in this offering. The placement agent warrants will have terms substantially similar to the warrants included in units offered hereby but provide for a cashless exercise feature.



Table of Contents

## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is quoted on the OTCQB under the symbol "SNGX." The following table sets forth, as adjusted for the reverse stock split of 1-for-20 effective February 1, 2012, for the periods indicated, the high and low sales prices per share of our common stock as reported by the OTCQB.

Period	High	Price Range	Low
Year Ended December 31, 2011:			
First Quarter	\$ 4.40		\$ 3.20
Second Quarter	\$ 5.20		\$ 3.60
Third Quarter	\$ 6.80		\$ 0.80
Fourth Quarter	\$ 1.00		\$ 0.60
Year Ended December 31, 2012:			
First Quarter	\$ 1.01		\$ 0.44
Second Quarter	\$ 0.53		\$ 0.23
Third Quarter	\$ 0.55		\$ 0.26
Fourth Quarter	\$ 0.77		\$ 0.38
Year Ending December 31, 2013:			
First Quarter	\$ 2.13		0.55

As of June 11, 2013, the last reported price of our common stock quoted on the OTCQB was \$1.85 per share. The OTCQB prices set forth above represent inter-dealer quotations, without adjustment for retail mark-up, mark-down or commission, and may not represent the prices of actual transactions. As of June 11, 2013, we have approximately 938 stockholders of record of our common stock.

**DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION  
FOR SECURITIES ACT LIABILITIES**

Section 102(b)(7) of the Delaware General Corporation Law allows companies to limit the personal liability of its directors to the company or its stockholders for monetary damages for breach of a fiduciary duty. Article IX of our Certificate of Incorporation, as amended, provides for the limitation of personal liability of our directors as follows:

"A Director of the Corporation shall have no personal liability to the Corporation or its stockholders for monetary damages for breach of his fiduciary duty as a Director; provided, however, this Article shall not eliminate or limit the liability of a Director (i) for any breach of the Director's duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the General Corporation Law of the State of Delaware; or (iv) for any transaction from which the Director derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended."

## Table of Contents

Article VIII of the our Bylaws, as amended and restated, provide for indemnification of directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

## EXPERTS

The consolidated balance sheets of Soligenix, Inc. as of December 31, 2012 and 2011 and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2012 have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein, in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

## LEGAL MATTERS

The validity of the shares of our common stock offered hereby will be passed upon by the law firm of Duane Morris LLP, Miami, Florida. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel to the placement agent in this offering.

## AVAILABLE INFORMATION

We have filed with the Securities and Exchange Commission, Washington, D.C. 20549, under the Securities Act of 1933, a registration statement on Form S-1 relating to the units offered hereby. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to our company and the units we are offering by this prospectus, you should refer to the registration statement, including the exhibits and schedules thereto. You may inspect a copy of the registration statement without charge at the Public Reference Section of the Securities and Exchange Commission at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission. The Securities and Exchange Commission also maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission. The Securities and Exchange Commission's World Wide Web address is <http://www.sec.gov>.

Statements contained in this prospectus as to the contents of any contract or other document that we have filed as an exhibit to the registration statement are qualified in their entirety by reference to the exhibits for a complete statement of their terms and conditions.

We file periodic reports, proxy statements and other information with the Securities and Exchange Commission in accordance with requirements of the Exchange Act. These periodic reports, proxy statements and other information are available for inspection and copying at the regional offices, public reference facilities and Internet site of the Securities and Exchange Commission referred to above. 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 Securities and Exchange Commission. Our website is located at <http://www.soligenix.com>. You can also request copies of such documents, free of charge, by contacting the company at (609) 538-8200 or sending an email to [info@soligenix.com](mailto:info@soligenix.com).

Information contained on our website is not a prospectus and does not constitute a part of this prospectus.

You should rely only on the information contained in or incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume the information in this prospectus is accurate as of any date other than the date on the front of this prospectus.

Table of Contents

INDEX TO FINANCIAL STATEMENTS  
SOLIGENIX, INC. AND SUBSIDIARIES  
CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

	Page
Consolidated Balance Sheets as of March 31, 2013 (unaudited) and December 31, 2012	F-2
Consolidated Statements of Operations for the Three Months Ended March 31, 2013 and 2012 (unaudited)	F-3
Consolidated Statements of Changes in Shareholders' Equity for the Three Months Ended March 31, 2013 (unaudited)	F-4
Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2013 and 2012 (unaudited)	F-5
Notes to Consolidated Financial Statements	F-6
Consolidated Balance Sheets as of December 31, 2012 and 2011	F-13
Consolidated Statements of Operations for the Years Ended December 31, 2012 and 2011	F-14
Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2012 and 2011	F-15
Consolidated Statements of Cash Flows for the Years Ended December 31, 2012 and 2011	F-16
Notes to Consolidated Financial Statements	F-17
Report of Independent Registered Public Accounting Firm	F-31

Table of ContentsSoligenix, Inc. and Subsidiaries  
Consolidated Balance Sheets

	March 31, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,612,021	\$ 3,356,380
Grants receivable	656,852	339,308
Prepaid expenses	170,778	140,693
Total current assets	3,439,651	3,836,381
Office furniture and equipment, net	11,539	12,995
Intangible assets, net	800,685	855,728
Total assets	\$ 4,251,875	\$ 4,705,104
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 1,651,740	\$ 1,124,503
Accrued compensation	24,063	29,495
Total current liabilities	1,675,803	1,153,998
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 350,000 shares authorized; none issued or outstanding		-
Common stock, \$.001 par value; 50,000,000 shares authorized; 11,194,968 shares and 11,168,905 shares issued and outstanding in 2013 and 2012, respectively	11,195	11,169
Additional paid-in capital	125,932,672	125,820,318
Accumulated deficit	(123,367,795 )	(122,280,381 )
Total shareholders' equity	2,576,072	3,551,106
Total liabilities and shareholders' equity	\$ 4,251,875	\$ 4,705,104

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

Soligenix, Inc. and Subsidiaries  
 Consolidated Statements of Operations  
 For the Three Months Ended March 31, 2013 and 2012  
 (Unaudited)

	Three Months Ended March 31,	
	2013	2012
Grant Revenue	\$900,354	\$647,418
Cost of revenues	(743,657 )	(556,571 )
Gross profit	156,697	90,847
<b>Operating expenses:</b>		
Research and development	756,653	876,794
General and administrative	487,941	655,043
Total operating expenses	1,244,594	1,531,837
Loss from operations	(1,087,897 )	(1,440,990 )
<b>Other income:</b>		
Interest income	483	2,235
Net loss	(1,087,414 )	(1,438,755 )
Basic and diluted net loss per share	\$(0.10 )	\$(0.13 )
Basic and diluted weighted average common shares outstanding	11,180,739	11,119,269

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

Soligenix, Inc. and Subsidiaries  
 Consolidated Statements of Changes in Shareholders' Equity  
 For the Three Months Ended March 31, 2013  
 (Unaudited)

	Common Stock Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Total
Balance, December 31, 2012	11,168,905	\$11,169	\$125,820,318	\$(122,280,381)	\$3,551,106
Issuance of restricted common stock to vendors	26,063	26	32,862	-	32,888
Stock-based compensation expense	-	-	79,492	-	79,492
Net loss	-	-	-	(1,087,414 )	(1,087,414)
Balance, March 31, 2013	11,194,968	\$11,195	\$125,932,672	\$(123,367,795)	\$2,576,072

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

Soligenix, Inc. and Subsidiaries  
Consolidated Statements of Cash Flows  
For the Three Months Ended March 31,  
(Unaudited)

	2013	2012
Operating activities:		
Net loss	\$(1,087,414)	\$(1,438,755)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	56,498	57,344
Restricted stock issued to employee	-	10,000
Restricted stock issued to vendors	32,888	-
Stock-based compensation	79,492	117,614
Change in operating assets and liabilities:		
Grants receivable	(317,544 )	38,068
Taxes receivable	-	574,157
Prepaid expenses	(30,085 )	51,726
Accounts payable	527,238	(72,999 )
Accrued compensation	(5,432 )	(12,690 )
Total adjustments	343,055	763,220
Net cash used in operating activities	(744,359 )	(675,535 )
Net decrease in cash and cash equivalents	(744,359 )	(675,535 )
Cash and cash equivalents at beginning of period	3,356,380	5,996,668
Cash and cash equivalents at end of period	\$2,612,021	\$5,321,133

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



Soligenix, Inc.  
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the “Company,” “we” or “us”) is a clinical stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense. Soligenix’s BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate (“BDP”) for the prevention/treatment of gastrointestinal (“GI”) disorders characterized by severe inflammation, including pediatric Crohn’s disease (SGX203), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator (“IDR”) technology (SGX942) for the treatment of oral mucositis. Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, and VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) therapeutic. The advanced development of these vaccine programs is currently supported by the Company’s heat stabilization technology, known as ThermoVax™, under existing and on-going grant funding.

The Company generates revenues under four active grants primarily from the National Institutes of Health (“NIH”).

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. Results for the quarter ended March 31, 2013 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of March 31, 2013, the Company had cash and cash equivalents of \$2,612,021 as compared to \$3,356,380 as of December 31, 2012, representing a decrease of \$744,359 or 22%. As of March 31, 2013, the Company had working capital of \$1,763,848 as compared to working capital of \$2,682,383 as of December 31, 2012, representing a decrease of \$918,535 or 34%. The decrease in cash and working capital was primarily due to cash used in operating activities. For the three months ended March 31, 2013, the Company’s cash used in operating activities was \$744,359 as compared to \$675,535 for the same period in 2012, representing an increase of \$68,824, or 10%.

Management’s business strategy can be outlined as follows:

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

Based on the Company's current rate of cash outflows, cash on hand and proceeds from its grant programs, and proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the second quarter of 2014.

F-6

---

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

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

The Company has approximately \$3.6 million in active grant funding still available to support its associated research programs through 2014 and beyond. The Company plans to submit additional grant applications for further support of its programs with various funding agencies.

The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.

The Company will pursue sale of Net Operating Losses ("NOLs") in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$521,458 in proceeds pursuant to NOL sales in 2012, the Company expects to participate in the program during 2013 and beyond; and

The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

## Note 2. Summary of Significant Accounting Policies

### Principles of Consolidation

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

### Operating Segments

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

### Grants Receivable

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

### Intangible Assets

One of the most significant estimates or judgments that the Company makes is whether to capitalize or expense patent and license costs. The Company makes this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, Research and Development. Based on this consideration, the Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for its current products in both the domestic and international markets. The Company believes that patent rights are one of its most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from Soligenix's

academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its products at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents and perhaps extending the lives of the patents. The Company capitalizes such costs and amortizes intangibles over their expected useful life – generally a period of 11 to 16 years.

The Company did not incur any capitalizable patent related costs during the quarters ended March 31, 2013 and 2012, respectively.

#### 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 quarters ended March 31, 2013 or 2012.

#### Fair Value of Financial Instruments

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

#### Revenue Recognition

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

#### Research and Development Costs

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

#### Stock-Based Compensation

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

Stock options are issued with an exercise price equal to the market price on the date of issuance. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon

issuance). Stock options issued to employees vest 25% immediately as of the grant date, then 25% each subsequent year for a period of three years. Stock options vest over each three month period from the date of issuance to the end of the three year period. These options have a ten year life for as long as the individuals remain employees or directors. In general when an employee or director terminates their position the options will expire within three months, unless otherwise extended by the Board.

Stock compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted is amortized as the options vest.

F-8

---

The Company did not issue any options during the quarters ending March 31, 2013 and 2012.

The fair value of options to be granted are estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods, which approximates the service period.

#### Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through March 31, 2013 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 2013 and 2012. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at March 31, 2013 and 2012. Tax years beginning in 2010 for federal purposes are generally subject to examination by taxing authorities, although net operating losses from those years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

#### Earnings Per Share

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

	Three Months Ended March 31,					
	Net Loss	2013 Shares	EPS	Net Loss	2012 Shares	EPS
Basic & Diluted EPS	\$ (1,087,414)	11,180,739	\$ (0.10 )	\$ (1,438,755)	11,119,269	\$ (0.13 )

Shares issuable upon the exercise of options and warrants outstanding at March 31, 2013 and 2012 were 1,454,755 and 1,496,898 and 2,843,338 and 2,576,341 shares, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2013 was \$3.20 and \$3.13 per share, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2012 was \$3.72 and \$4.32 per share, respectively. No options or warrants were included in the 2013 and 2012 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

#### Use of Estimates and Assumptions

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

F-9

---



## Note 3. Intangible Assets

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

	Weighted Average Remaining Amortization Period (years)	Cost	Accumulated Amortization	Net Book Value
March 31, 2013				
Licenses	7.5	\$ 462,234	\$ 258,737	\$ 203,497
Patents	3.2	1,893,185	1,295,997	597,188
Total	4.0	\$ 2,355,419	\$ 1,554,734	\$ 800,685
December 31, 2012				
Licenses	7.7	\$ 462,234	\$ 252,019	\$ 210,215
Patents	3.3	1,893,185	1,247,672	645,513
Total	4.2	\$ 2,355,419	\$ 1,499,691	\$ 855,728

Amortization expense was \$55,043 and \$55,654 for the three months ended March 31, 2013 and 2012, respectively.

Based on the balance of licenses and patents at March 31, 2013, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
2013	\$ 222,800
2014	\$ 222,800
2015	\$ 133,000
2016	\$ 61,800
2017	\$ 20,800

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

#### Note 4. Income Taxes

The Company had NOLs at December 31, 2012 of approximately \$79,463,000 for federal tax purposes and approximately \$9,498,000 of New Jersey NOL carry forwards remaining after the sale of unused NOL carry forwards, portions of which are currently expiring each year until 2031. In addition, the Company had \$3,068,000 of various tax credits that started expiring in December 2012 and will continue to expire through December 2030. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code (“IRC”) Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL 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 possible that the utilization of the NOLs, could 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 Federal income tax assessment for years before 2010 for Federal and 2009 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination and adjustments by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

The Company has no tax provision for the three month periods ended March 31, 2013 and 2012 due to losses and full valuation allowances against net deferred tax assets.

#### Note 5. Shareholders’ Equity

##### Preferred Stock

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

##### Common Stock

During the three months ended March 31, 2013, the Company issued 26,063 shares of common stock to vendors as partial consideration for services performed.

#### Note 6. Commitments and Contingencies

The Company has commitments of approximately \$368,800 as of March 31, 2013 for several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

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

In February 2007, the Company’s Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by the its Board of Directors whereby, directly or indirectly, a majority of the its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 50,000 common shares to Dr. Schaber and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes its

obligation to issue such shares if such event occurs.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment. The Company recognized an expense of \$95,625 during the quarter ended March 31, 2012 related to severance and healthcare benefits paid to the prior Chief Financial Officer of the Company.

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

Year	Research and Development	Property and Other Leases	Total
2013	\$ 43,800	\$ 79,100	\$ 122,900
2014	100,000	101,200	201,200
2015	75,000	25,000	100,000
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	\$ 368,800	\$ 205,300	\$ 574,100

## Note 7. Operating Segments

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

	Three Months Ended March 31,	
	2013	2012
Grant Revenue		
Vaccines/BioDefense	\$ 829,849	\$ 597,605
BioTherapeutics	70,505	49,813
Total	\$ 900,354	\$ 647,418
Loss from Operations		
Vaccines/BioDefense	\$ (30,955 )	\$ (128,366 )
BioTherapeutics	(457,625 )	(726,042 )
Corporate	(599,277 )	(586,582 )
Total	\$ (1,087,897)	\$ (1,440,990)
Amortization and Depreciation Expense		
Vaccines/BioDefense	\$ 27,667	\$ 27,997
BioTherapeutics	28,395	28,840
Corporate	436	507
Total	\$ 56,498	\$ 57,344
Interest Income		
Corporate	\$ 483	\$ 2,235
Stock-Based Compensation		
Vaccines/BioDefense	\$ 11,121	\$ 2,130
BioTherapeutics	21,036	56,240
Corporate	47,335	59,064
Total	\$ 79,492	\$ 117,614
	As of	As of
	March 31,	December
	2013	31,
		2012
Identifiable Assets		
Vaccines/BioDefense	\$936,695	\$628,494
BioTherapeutics	519,391	566,111
Corporate	2,795,789	3,510,499
Total	\$4,251,875	\$4,705,104

## Note 8. Subsequent Event

On April 27, 2013, the Company entered into a Stock Issuance Agreement with Intrexon Corporation ("Intrexon"), pursuant to which the Company has issued to Intrexon 1,034,483 shares of Common Stock in consideration for the

execution and delivery of an Exclusive Channel Agreement (the "Channel Agreement"). The shares issued to Intrexon represent approximately 8.5% of the issued and outstanding shares of Common Stock as of April 27, 2013.

The Channel Agreement with Intrexon enables the Company to use Intrexon's advanced human antibody discovery, isolation, and production technologies for the development and commercialization of human monoclonal antibody therapies for a new biodefense and infectious disease application.

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

	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,356,380	\$ 5,996,668
Grants receivable	339,308	362,473
Taxes receivable	-	574,157
Prepaid expenses	140,693	195,762
Total current assets	3,836,381	7,129,060
Office furniture and equipment, net	12,995	15,032
Intangible assets, net	855,728	1,079,566
Total assets	\$ 4,705,104	\$ 8,223,658
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 1,124,503	\$ 1,303,555
Accrued compensation	29,495	129,061
Total current liabilities	1,153,998	1,432,616
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 350,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 50,000,000 and 20,000,000 shares authorized in 2012 and 2011, respectively; 11,168,905 shares and 11,105,532 shares issued and outstanding in 2012 and 2011, respectively (1)	11,169	11,106
Additional paid-in capital (1)	125,820,318	124,897,309
Accumulated deficit	(122,280,381 )	(118,117,373 )
Total shareholders' equity	3,551,106	6,791,042
Total liabilities and shareholders' equity	\$ 4,705,104	\$ 8,223,658

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

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

Table of Contents

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

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

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

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

Table of Contents

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

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

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

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



Table of Contents

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

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

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

Table of Contents

Soligenix, Inc. and Subsidiaries  
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the “Company”) is a clinical stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat the life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense. Soligenix’s BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate (“BDP”) for the prevention/treatment of gastrointestinal (“GI”) disorders characterized by severe inflammation, including pediatric Crohn’s disease (SGX203), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator (“IDR”) technology (SGX942) for the treatment of oral mucositis. On September 15, 2011 the Company’s confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease (“GI GVHD”) was stopped at the recommendation of an independent Data Safety Monitoring Board (“DSMB”). Our Vaccines/BioDefense business segment includes RiVax™, our ricin toxin vaccine, and VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) program. The advanced development of these programs will be supported by our existing and on-going government grants, including our National Institutes of Health (“NIH”) grant for our heat stabilization technology ThermoVax™.

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

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

Liquidity

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

Management’s business plan can be outlined as follows:

Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;

Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;

F-17

---

## Table of Contents

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

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

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

Explore other business development and merger/acquisition strategies.

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

The Company has approximately \$3.8 million in active grant funding still available to support its associated research programs through 2014 and beyond. The Company plans to submit additional grant applications for further support of its programs with various funding agencies.

The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.

The Company will pursue Net Operating Losses ("NOLs") sales in the State of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$521,458 in proceeds pursuant to NOLs sales in 2012, the Company expects to participate in the program during 2013 and beyond; and

The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

## Reverse Stock Split

On February 1, 2012, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1-for-20, whereby, once effective, every 20 shares of its common stock was exchanged for one share of its common stock. Its common stock began trading on the OTCBB on a reverse split basis at the market opening on February 2, 2012. All share and per share data reflects this reverse stock split.

## Note 2. Summary of Significant Accounting Policies

### Principles of Consolidation

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

### Operating Segments

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

F-18

---

## Table of Contents

### Grants Receivable

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

### Intangible Assets

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

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

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

### Impairment of Long-Lived Assets

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

The Company did not record any impairment of long-lived assets for the years ended December 31, 2012 or 2011, except for the patent write-offs discussed in Note 3.

### Fair Value of Financial Instruments

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



## Table of Contents

### Revenue Recognition

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

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

### Research and Development Costs

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

### Stock-Based Compensation

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

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

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

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



a dividend yield of 0%;

an expected life of 4 years;

volatilities of 160% for 2012 and ranging from 123% to 160% for 2011;

F-20

---

Table of Contents

forfeitures at a rate of 12%; and

risk-free interest rates of 0.51% for 2012 and 0.69% to 1.47% in 2011.

The fair value of each option grant made during 2012 and 2011 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods, which approximates the service period.

## Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through December 31, 2012 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2012 and 2011. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2012 and 2011. Tax years beginning in 2009 for federal purposes are generally subject to examination by taxing authorities, although net operating losses from those years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

## Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented. No options and warrants were included in the 2012 and 2011 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses or options and warrants for which the strike price exceeds the quoted market value at period end.

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

Shares issuable upon the exercise of options and warrants outstanding at December 31, 2012 and 2011 were 1,457,724 and 1,544,242 shares issuable upon the exercise of options, and 2,843,338 and 2,701,569 shares issuable upon the exercise of warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at December 31, 2012 were \$3.19 and \$3.13 per share, respectively. No options or warrants were included in the 2012 and 2011 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.



Table of Contents

## Use of Estimates and Assumptions

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

## Note 3. Intangible Assets

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

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

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

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

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

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

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

Table of Contents

## Note 4. Income Taxes

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

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

At December 31, 2012, the Company had NOL carry forwards of approximately \$79,463,000 for federal tax purposes and approximately \$9,498,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which are currently expiring each year through 2032. In addition, the Company has \$3,068,000 of various tax credits that expire from 2013 to 2032. The Company may be able to utilize their NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code (“IRC”) Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carry forwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to Federal income tax assessment for years before 2008 for Federal and 2007 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination and adjustments by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

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

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2012 and 2011 was as follows:

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

During the years ended December 31, 2012 and 2011, in accordance with the State of New Jersey’s Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused net operating loss carryforwards to other New Jersey-based corporate taxpayers based in New Jersey, the Company sold New Jersey net operating loss carryforwards, resulting in the recognition of \$521,458 and \$574,157 of income tax benefit, net of transaction costs, respectively. There can be no assurance as to the continuation or magnitude of this

program in future.

F-23

---

Table of Contents

The Company follows FASB ASC 740-10, Uncertainty in Income Taxes. The Company recognizes interest and penalties associated with uncertain tax positions as a component of income tax expense. The Company does not expect that there will be any amounts of unrecognized tax benefits in the next 12 months. This standard prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company did not have any unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2012 and 2011. The Company does not expect to have any unrecognized tax benefits within the next twelve months. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2012 and 2011.

Note 5. Shareholders' Equity

Preferred Stock

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

Common Stock

The following items represent transactions in the Company's common stock for the year ended December 31, 2012:

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

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

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

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

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

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

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

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

## Table of Contents

### Warrants

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

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

### Equity Line

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

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

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

The Fusion equity line expired in October 2011.

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

#### Stock Option Plans

The Amended and Restated 1995 Omnibus Plan was replaced by the 2005 Equity Incentive Plan and is divided into four separate equity programs:



- 1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock,
- 2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock,
- 3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, 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.

Table of Contents

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

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

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

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

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

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

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

Table of Contents

As of December 31, 2012, there were 1,191,474 options exercisable with a weighted average exercise price of \$3.51, a weighted average remaining contractual term of 8.6 years and an intrinsic value of \$15,000. As of December 31, 2012, there were 1,457,724 options exercisable or expected to vest with a weighted average exercise price of \$3.19, weighted average remaining contractual term of 7.0 years and an intrinsic value of \$30,000. The aggregate intrinsic value represents the total pre-tax intrinsic value (the difference between the closing price of our common stock on the last trading day of 2012 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2012. This amount changes based on the fair market value of our common stock.

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

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

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

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

## Warrants to Purchase Common stock

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

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

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

F-27

---

Table of Contents

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

Price Range	Weighted Average Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
\$ .53-\$2.00	5.0	777,373	777,373
\$2.80-\$3.96	1.1	1,103,202	1,103,202
\$5.00-\$6.06	2.2	962,763	962,763
Total	2.5	2,843,338	2,843,338

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

## Note 7. Concentrations

At December 31, 2012 and 2011, the Company had deposits in major financial institutions that exceeded the amount under protection by the Securities Investor Protection Corporation ("SIPC"). Currently, the Company is covered up to \$1,000,000 by the SIPC. The excess amounts at December 31, 2012 and 2011 were \$2,356,380 and \$4,996,668, respectively.

## Note 8. Commitments and Contingencies

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

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

In February 2007, the Company's Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 50,000 common shares to Dr. Schaber and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes its obligation to issue such shares if such event occurs.

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



Table of Contents

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

Year	Research and Development	Property and Other Leases	Total
2013	\$ 100,000	\$ 105,000	\$ 205,000
2014	100,000	101,200	201,200
2015	75,000	25,000	100,000
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	\$ 425,000	\$ 231,200	\$ 656,200

Table of Contents

## Note 9. Operating Segments

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

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

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



Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders,

We have audited the accompanying consolidated balance sheets of Soligenix, Inc. and subsidiaries (the “Company”) as of December 31, 2012 and 2011, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for each of the years in the two-year period ended December 31, 2012. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Soligenix, Inc. and subsidiaries as of December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Jenkintown, PA  
February 25, 2013

Table of Contents

---

---

Until \_\_\_\_\_, 2013, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

No dealer, salesperson or any other person is authorized to give any information or make any representations in connection with this offering other than those contained in this prospectus and, if given or made, the information or representations must not be relied upon as having been authorized by us. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any security other than the securities offered by this prospectus, or an offer to sell or a solicitation of an offer to buy any securities by anyone in any jurisdiction in which the offer or solicitation is not authorized or is unlawful.

SOLIGENIX, INC.

Best Efforts Offering

UP TO 5,405,405 UNITS, EACH CONSISTING OF  
ONE SHARE OF COMMON STOCK,  
A WARRANT TO PURCHASE UP TO AN ADDITIONAL 0.75 SHARE OF COMMON STOCK AND A  
PREFERRED STOCK PURCHASE RIGHT

---

PROSPECTUS

---

Lead managing placement agent

Maxim Group LLC

, 2013

---

---

Table of Contents

## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

## ITEM Other Expenses of Issuance and Distribution.

13.

The following table sets forth the estimated costs and expenses of the Registrant in connection with the offering described in the registration statement. All of the amounts shown are estimated except for the Securities and Exchange Commission (the "SEC") registration fee.

SEC registration fee	\$ 1,346
Legal fees and expenses	\$ 250,000
Accounting fees and expenses	\$ 27,000
Miscellaneous	\$ 5,000
<b>TOTAL</b>	<b>\$ 283,346</b>

## ITEM Indemnification of Directors and Officers.

14.

Section 145(a) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or other adjudicating court shall deem proper.

Section 145(g) of the Delaware General Corporation Law provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by

such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the Delaware General Corporation Law.

II-1

---

Table of Contents

Section 102(b)(7) of the Delaware General Corporation Law grants the Registrant the power to limit the personal liability of its directors to the Registrant or its stockholders for monetary damages for breach of a fiduciary duty. Article X of the Registrant's Certificate of Incorporation, as amended, provides for the limitation of personal liability of the directors of the Registrant as follows:

"A Director of the Corporation shall have no personal liability to the corporation or its stockholders for monetary damages for breach of his fiduciary duty as a Director; provided, however, this Article shall not eliminate or limit the liability of a Director (i) for any breach of the Director's duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the General Corporation Law of the State of Delaware; or (iv) for any transaction from which the Director derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended."

Article VIII of the Registrant's Bylaws, as amended and restated, provide for indemnification of directors and officers to the fullest extent permitted by Section 145 of the Delaware General Corporation Law.

The Registrant has a directors' and officers' liability insurance policy.

The above discussion is qualified in its entirety by reference to the Registrant's Certificate of Incorporation and Bylaws.

ITEM Recent Sales of Unregistered Securities.

15.

In sixteen separate transactions during the year ended December 31, 2011, the Registrant issued an aggregate of 90,789 shares of common stock under the common stock purchase agreement with Fusion Capital. The purchase price was calculated in accordance with the formula set forth in the purchase agreement. The Registrant received an aggregate of \$355,000 in proceeds which approximated the shares' fair market value on the dates of issuance. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as a transaction not involving a public offering.

On July 26, 2011, as a result of granting Sigma-Tau an exclusive license to commercialize orBec® in the European Territory, the Registrant amended the license agreement with Dr. George McDonald and issued 66,890 shares of common stock in lieu of a \$400,000 cash obligation. The purchase price was based upon the closing price of \$5.98 on July 26, 2011. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as a transaction not involving a public offering.

On November 10, 2011, the Registrant issued 25,625 shares of common stock in connection with an employee's severance from the Registrant. The closing price of the Registrant's common stock on November 10, 2011 was \$0.80 per share. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as a transaction not involving a public offering.

On December 19, 2011, the Registrant issued 29,297 shares of its common stock to a consultant as partial consideration for services rendered. The closing price of the Registrant's common stock on December 19, 2011 was \$0.53 per share. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as a transaction not involving a public offering.

On January 10, 2013, the Registrant issued 11,063 shares of common stock to a consultant as partial consideration for services performed. The per share closing price of the Company's common stock on December 30, 2012 was \$0.60. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

On March 13, 2013, the Registrant issued 15,000 shares of common stock to a vendor as partial consideration for services performed. The per share closing price of the Company's common stock on March 13, 2013 was \$1.75. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

On April 27, 2013, the Registrant issued 1,034,483 shares of its common stock to Intrexon as consideration for the execution and delivery of a collaboration agreement. The closing price of the Registrant's common stock on April 26, 2013 was \$1.45 per share. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as a transaction not involving a public offering.

II-2

---

Table of Contents

ITEM Exhibits.

16.

- 1.1 Form of Placement Agency Agreement, between the Company Maxim Group LLC. \*
- 2.1 Agreement and Plan of Merger, dated May 10, 2006 by and among the Company, Corporate Technology Development, Inc., Enteron Pharmaceuticals, Inc. and CTD Acquisition, Inc. (incorporated by reference to Exhibit 2.1 included in our Registration Statement on Form SB-2 (File No. 333-133975) filed on May 10, 2006).
- 3.1 Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2012).
- 3.2 By-laws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003).
- 4.1 Rights Agreement dated June 22, 2007, between the Company and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on June 22, 2007).
- 4.2 Form of Right Certificate (incorporated by reference to Exhibit 4.2 included in our current report on Form 8-K filed on June 22, 2007).
- 4.3 Form of Warrant issued to each investor in the January 2009 private placement (incorporated by reference to Exhibit 4.18 included in our Registration Statement on Form S-1 (File No. 333-149239) filed on February 14, 2008).
- 4.4 Form of Warrant issued to each investor in the September 2009 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on September 29, 2009).
- 4.5 Warrant dated April 19, 2010, issued to Fusion Capital Fund II, LLC (incorporated by reference to Exhibit 4.10 included in our Post-Effective Amendment to Registration Statement on Form S-1 filed on April 20, 2010).
- 4.6 Form of Common Stock Purchase Warrant issued to each investor in the June 2010 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on June 18, 2010).
- 5.1 Opinion of Duane Morris LLP. \*
- 10.1 Amended and Restated 1995 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003). \*\*
- 10.2 License Agreement between the Company and the University of Texas Southwestern Medical Center (incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB filed March 30, 2004, as amended, for the fiscal year ended December 31, 2004).
- 10.3 License Agreement between the Company and Thomas Jefferson University (incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended

December 31, 2004).

- 10.4 License Agreement between the Company and the University of Texas Medical Branch (incorporated by reference to Exhibit 10.10 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).
- 10.5 Consulting Agreement between the Company and Lance Simpson of Thomas Jefferson University. (incorporated by reference to Exhibit 10.43 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).
- 10.6 2005 Equity Incentive Plan (incorporated by reference to Appendix D to our Proxy Statement filed December 12, 2005). \*\*
- 10.7 Form S-8 Registration of Stock Options Plan dated December 30, 2005 (incorporated by reference to our registration statement on Form S-8 filed on December 30, 2005).

II-3

---



Table of Contents

- 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).