SOLIGENIX, INC.
Form S-1
November 05, 2012
As filed with the Securities and Exchange Commission on November 5, 2012.

Registration No.

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Delaware	2834	41-1505029
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(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.

Edwards Wildman Palmer LLP
525 Okeechobee Blvd., Suite 1600
West Palm Beach, Florida 33401
(561) 833-7700

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: x

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. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company x
(Do not check if a smaller reporting company)	

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CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price	Amount of registration fee(1)	
Units, each unit consisting of one share of Common Stock, $0.001 par value, and a warrant to purchase up to an additional _____ share of Common Stock	$ 7,000,000	$ 955	
Common Stock included in the Units	$ —	$ —	
Warrants included in the Units	$ —	—	(3)
Common Stock issuable upon exercise of the warrants included in the Units (2)	$ —	—	(3)
Series A Junior Participating Preferred Stock Purchase Rights (4)			
Total	$ 7,000,000	$ 955	

(1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered.

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon exercise of warrants registered hereunder as a result of stock splits, stock dividends, or similar transactions.

(3) No fee required pursuant to Rule 457(g).

(4) This registration statement also covers the Preferred Share Purchase Rights issuable in accordance with the Rights Agreement, dated June 22, 2007, between the Registrant and American Stock Transfer & Trust Company, as Rights Agent, which are presently attached to and trade with the Registrant's common stock.

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.

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The information in this prospectus is not complete and may be changed. The Selling Stockholders 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.

SUBJECT TO COMPLETION, DATED NOVEMBER 5, 2012

PROSPECTUS

SOLIGENIX, INC.

UP TO _____ UNITS, EACH CONSISTING OF
ONE SHARE OF COMMON STOCK AND
WARRANTS TO PURCHASE UP TO AN ADDITIONAL _____ SHARE OF COMMON STOCK

We are offering up to _____ units (each a "Unit" and collectively the "Units"), each Unit consisting of one share of our common stock and a warrant to purchase up to an additional _____ share of our common stock. The warrants entitle holders to purchase one share of our common stock for each _____ warrants 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. We are not required to sell any specific dollar amount or number of Units, but will use our best efforts to sell all of the Units being offered. The offering expires on the earlier of (i) the date upon which all of the Units being offered have been sold, or (ii) March 31, 2013. 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 presently listed on the OTCQB under the symbol "SNGX". OTCQB securities are quoted on OTC Market Group's quotation and trading system. We do not intend to apply for listing of the warrants on any securities exchange. On October 31, 2012, the last quoted sale price of our common stock as reported on the OTCQB was $0.44 per share.

INVESTING IN THE OFFERED SECURITIES INVOLVES RISKS, INCLUDING THOSE SET FORTH IN THE "RISK FACTORS" SECTION OF THIS PROSPECTUS BEGINNING ON PAGE 5.

	Per Unit	Total
Offering Price per Unit	$_____	$_____
Placement Agent's Fees	$_____	$_____
Offering Proceeds before expenses	$_____	$_____

_____ 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 __% of the gross proceeds of the offering of Units by us, as well as "placement agent warrants" to purchase shares of our common stock equal to _____% of the aggregate number of shares of common stock included in Units sold in the offering. The placement agent warrants will have terms substantially similar to the warrants included in Units offered hereby. We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately $_____. 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 46 of this prospectus for more information on this offering and the placement agent arrangements.

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This offering will terminate on March 31, 2013, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. All costs associated with the registration will be borne by us.

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.

The Units stock may be sold directly by us to investors, through our placement agent or to or through underwriters or dealers. See "Plan of Distribution". If any underwriters are involved in the sale of any Units in respect of which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The net proceeds we expect to receive from such sale also will be set forth in a prospectus supplement.

Brokers or dealers effecting transactions in these Units should confirm that the Units are registered under the applicable state law or that an exemption from registration is available.

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

The date of this prospectus is _____, 2012

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You should rely only on the information contained or incorporated by reference in this prospectus and in any accompanying prospectus supplement. 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 or prospectus supplement is accurate as of any date other than the date on the front of this prospectus.

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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" 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;
- significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;
- our ability to obtain regulatory approvals;
- uncertainty as to whether our technologies will be safe and effective;
- our ability to obtain future financing or funds when needed;
- 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 successfully 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;
- changes in healthcare regulation;
- changes in the needs of biodefense procurement agencies;
- maintenance of a successful business strategy;
- the possibility that our products under development may not gain market acceptance; and
- 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.

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PROSPECTUS SUMMARY

SOLIGENIX, INC.

UP TO _____ UNITS, EACH CONSISTING OF
ONE SHARE OF COMMON STOCK AND
WARRANTS TO PURCHASE UP TO AN ADDITIONAL _____ SHARE OF COMMON STOCK

About this Prospectus

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,” “Company” and “Soligenix” refer to Soligenix, Inc. Y should read both this prospectus and any prospectus supplement together with additional information described below under the heading "Where You Can Find More Information".

About our Company

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

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

An outline of our business strategy follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203, in pediatric Crohn’s disease;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal (“GI”) tract such as prevention of acute radiation enteritis 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 Vaccines/BioDefense programs through grants, contracts and/or procurements;
- Acquire or in-license new clinical-stage compounds for development; and
- Explore other business development and acquisition strategies.

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

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical program planned
SGX201	Acute Radiation Enteritis	Phase 1/2 trial complete; safety and preliminary efficacy demonstrated
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned
LPM™ Leuprolide	Endometriosis and Prostate Cancer	Pre-clinical

Vaccine Thermostability Platform

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

Vaccines/BioDefense Products

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

Summary of the Offering

Securities Offered	Up to _____ Units. Each Unit will consist of one share of our common stock and a warrant to purchase up to an additional _____ shares of our common stock. Units may be issued and sold in one or more closings up to the termination date, March 31, 2013.
Offering Price	$_____ 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 _____ shares.
Prior to the Offering

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Common Stock Outstanding After the Offering	_____ shares, which does not include _____ shares of common stock issuable upon exercise of the warrants included in the offered Units.
Over-Allotment Option	The placement agent will have a 30-day option to arrange for the sale of up to an additional _____% of the total Units sold (consisting of _____ shares and warrants to purchase _____ shares of common stock) to cover over-allotments.
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 5 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in the Units.

The total number of shares of our common stock outstanding as of October 31, 2012 was 11,160,513, which excludes the following:

129,711 shares of common stock reserved for future issuance under our equity incentive plans. As of October 31, 2012, there were options to purchase 1,475,224 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of $3.22 per share;

2,576,341 shares of common stock issuable upon exercise of outstanding warrants as of October 31, 2012 with a weighted average exercise price of $4.32 per share; and

_____ 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.

All information in this prospectus assumes the placement agent does not sell any Units contained in the over-allotment option.

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RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. Any of the factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock. Below are the significant risks and uncertainties of which we are aware. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in and incorporated by reference into 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 have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of September 30, 2012, we have approximately $3.7 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 fourth quarter of 2013.

We have sufficient funds through our existing biodefense grant facilities from the National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institutes of Health (“NIH”), to finance our biodefense projects for the next several years. In September 2009, we received a NIAID grant for approximately $9.4 million for the development of our biodefense programs and recently received an additional NIAID Small Business Innovation and Research (“SBIR”) grant 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 September 2012, we have expended approximately $45.0 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least $2 million over the next two years in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs.

If we are unsuccessful in developing our products, our ability to generate revenues will be significantly impaired.

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and pre-clinical development and will require significant further funding, research, development, pre-clinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure

inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

- we may not be able to maintain our current research and development schedules;
- we may be unsuccessful in our efforts to secure profitable procurement contracts from the U.S. government or others for our biodefense products;

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we may encounter problems in clinical trials; or
the technology or product may be found to be ineffective or unsafe.

If any of the risks set forth above occur, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may not be able to successfully develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of any other technology we develop, even if it is shown to be effective, if:

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

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

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

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. For example, our confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD") was stopped on September 15, 2011 at the recommendation of an independent Data Safety Monitoring Board ("DSMB") as it was highly unlikely to achieve the predetermined end point of efficacy based on the interim results. Although no safety concerns were raised by the DSMB, preliminary findings indicated that there were no significant differences between the orBec® group and placebo group for the primary endpoint or for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, the Company terminated the development of orBec® for the treatment of acute GI GVHD. Although we hope to obtain FDA approval for orBec® in a similar indication of treatment of chronic GI GVHD, there can be no assurances that the FDA will ever approve orBec® for market launch.

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

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

There may be unforeseen challenges in developing our biodefense products.

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

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

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our successful receipt of government funding is also dependant on our ability to adhere to the terms and provisions of the original grant documents and other regulations.

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

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

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

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

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

We do not have experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. Although we have a collaboration agreement with Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) for the sales and marketing of orBec® in North America and Europe, we may be unable to establish additional satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for orBec® or our other product candidates. In addition, Sigma-Tau may not be able to effectively commercialize orBec® if it is approved. To obtain the expertise necessary to successfully market and sell orBec®, or any other product, potentially will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

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

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

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

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

In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations.

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

have a material adverse effect on our business, financial condition and profitability.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that are currently separately billed. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. We cannot speculate on the potential sales impact to orBec® based on the new rule.

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

We currently rely on license agreements from the University of Texas Southwestern Medical Center, Harvard University, the University of Colorado, and George B. McDonald, MD for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, or at all.

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

Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force. If our collaboration agreement with Sigma-Tau were to be terminated, we would need to establish and build our own sales force in North America and Europe or enter into an agreement for the commercialization of orBec® with another company. Development of an effective sales force in any part of the world would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

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

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

We may not be able to compete successfully with our competitors in the biotechnology industry.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Most of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in

the therapeutic area of inflammatory bowel diseases. We face intense competition in the biodefense area from various public and private companies and universities as well as governmental agencies, such as the U.S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete successfully with our existing and future competitors.

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

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

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

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

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

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

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

We currently have only 9 employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. We will not be successful if our management team cannot effectively manage and operate our business.

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

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

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

Risks Related to our Common Stock

Our common stock price is highly volatile.

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

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

Since January 1, 2012, the closing stock price (split adjusted) has fluctuated between a high of $0.80 per share to a low of $0.23 per share. As of October 31, 2012, our common stock closed at $0.44 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock by the Company, as well as the 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 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 Securities and Exchange Commission ("SEC") and other regulatory authorities.

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

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

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

- warrants to purchase a total of approximately 2,576,341 shares of our common stock at a current weighted average exercise price of approximately $4.32; and
- options to purchase approximately 1,475,224 shares of our common stock at a current weighted average exercise price of approximately $3.22.

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

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

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

USE OF PROCEEDS

We estimate that we will receive up to $_____ in net proceeds from the sale of Units in this offering, based on an assumed price of $_____ per Unit and after deducting estimated placement agent 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.

DILUTION

If you purchase Units in this offering, and assuming no value is attributed to the warrants, your interest will be diluted immediately to the extent of the difference between the assumed public offering price of $_____ 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 September 30, 2012 was approximately $3.1 million, or approximately $0.28 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 September 30, 2012.

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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. After giving effect to our sale of up to _____ Units in this offering at an assumed public offering price of $_____ per Unit, and after deducting the placement agent commissions and estimated offering expenses, our as adjusted net tangible book value as of September 30, 2012 would have been $_____ million, or $_____ per share. This represents an immediate increase in net tangible book value of $_____ per share to existing stockholders and an immediate dilution in net tangible book value of $_____ per Unit to purchasers of Units in this offering, as illustrated in the following table:

Assumed public offering price per Unit	$	____
Net tangible book value per share as of September 30, 2012	$0.28	
Increase in net tangible book value per Unit attributable to new investors	$	____
Adjusted net tangible book value per share as of September 30, 2012, after giving effect to the offering	$	____
Dilution per Unit to new investors in the offering	$	____

The above discussion and tables do not include the following:

- 129,711 shares of common stock reserved for future issuance under our equity incentive plans. As of October 31, 2012, there were options to purchase 1,475,224 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of $3.22 per share;
- 2,576,341 shares of common stock issuable upon exercise of outstanding warrants as of October 31, 2012 with a weighted average exercise price of $4.32 per share; and
- _____ 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.

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BUSINESS

Our Business Overview

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

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

An outline of our business strategy follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203, in pediatric Crohn's disease;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute radiation enteritis 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 Vaccines/BioDefense programs through grants, contracts and/or procurements;
- Acquire or in-license new clinical-stage compounds for development; and
- Explore other business development and acquisition strategies.

Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Our Products in Development

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

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical program planned
SGX201	Acute Radiation Enteritis	Phase 1/2 trial complete; safety and preliminary efficacy demonstrated
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned
LPM™ Leuprolide		Pre-clinical

Endometriosis and Prostate Cancer

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Vaccine Thermostability Platform

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

Vaccines/BioDefense Products

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

BioTherapeutics Overview

orBec® and Oral BDP

orBec®/oral BDP 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. orBec®/oral BDPis 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.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, orBec®/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.

Commercialization and Market

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau for the commercialization of orBec®/oral BDP. Sigma-Tau is a pharmaceutical company that develops novel therapies for the unmet needs of patients with rare diseases. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec®/oral BDP in the U.S., Canada and Mexico (“the Territory”). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. Total remaining milestone payments due from Sigma-Tau for orBec®/oral BDP under the agreement could reach up to $9 million. Sigma-Tau will pay us a 35% royalty (Soligenix to provide finished drug product) on net sales in the Territory as well as pay for commercialization expenses, including launch activities.

The Collaboration and Supply Agreement with Sigma-Tau expires on a country-by-country basis on the later of: (i) 10 years after the date of the first commercial sale of orBec®/oral BDP by Sigma-Tau in such country; or (ii) the expiration of the last to expire of the Company’s patents and patent applications relating to orBec®/oral BDP in such country. Upon the expiration of the initial term, on a country-by-country basis, the agreement is automatically

renewed for periods of five years. During such renewal periods, we and Sigma-Tau have the right to terminate the agreement for convenience upon six months and 18 months, respectively, prior written notice. If we terminate the agreement for convenience, we are required to transfer to Sigma-Tau or its designee, for no consideration, the U.S. Food and Drug Administration ("the FDA") and European Medicines Agency ("EMEA") authorizations which are necessary for the marketing, use, distribution and sale of orBec®/oral BDP and all relevant data and know-how necessary to manufacture and commercialize orBec®/oral BDP in the country and grant to Sigma-Tau a royalty-free, fully paid, perpetual and irrevocable license, with the right to sublicense, to all trademarks and such know-how.

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

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

On July 28, 2011, we announced the expansion and amendment of our North American licensing partnership with Sigma-Tau for the development and commercialization of orBec®/oral BDP into the “European Territory” (as defined in the amendment). Pursuant to this amendment, we received an up-front non-refundable payment of $5 million and granted Sigma-Tau an exclusive license to commercialize orBec®/oral BDP in the European territory. The amendment requires Sigma-Tau to make additional payments to us in the aggregate amount of $11 million upon the achievement of certain milestones. The amendment also requires Sigma-Tau to pay us a 40% royalty (Soligenix to provide finished drug product) on net sales in the European Territory and pay for all commercialization expenses, including launch activities.

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

Future Potential Indications of orBec® and Oral BDP

Based on its pharmacological characteristics, orBec®/oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent 8,263,582 claiming the use of oral BDP as a method of treating inflammatory disorders, including Crohn’s disease, of the gastrointestinal tract 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 HCT, 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 and European patent EP 1830857 claiming oral BDP in conjunction with a short duration of high-dose prednisone with a rapid taper for the reduction of mortality associated with GVHD and leukemia. We are planning for/pursuing 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 exploring the possibility of testing oral BDP (the active ingredient in orBec®) for local inflammation associated with Ulcerative Colitis, among other indications.

SGX203 – Oral BDP for Treating Pediatric Crohn’s Disease

SGX203 is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has awarded SGX203 Orphan Drug Designation for the treatment of pediatric Crohn's disease. We plan to initiate a Phase 2 clinical trial in pediatric Crohn’s disease in 2012.

About Pediatric Crohn's Disease

Crohn's disease is an ongoing disorder that causes inflammation of the GI tract. Crohn's disease can affect any area of the GI tract, from the mouth to the anus, but it most commonly affects the lower part of the small intestine, called the ileum. The swelling caused by the disease extends deep into the lining of the affected organ. The swelling can induce

pain and can make the intestines empty frequently, resulting in diarrhea. Because the symptoms of Crohn's disease are similar to other intestinal disorders, such as irritable bowel syndrome and ulcerative colitis, it can be difficult to diagnose. People of Ashkenazy Jewish heritage have an increased risk of developing Crohn's disease.

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Crohn's disease can appear at any age, but it is most often diagnosed in adults in their 20s and 30s. However, approximately 30% of people with Crohn's disease develop symptoms before 20 years of age. Pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the United States. Crohn's disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (25-40%) of pediatric Crohn's patients have involvement of their upper gastrointestinal tract.

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

SGX201 - Oral BDP for Preventing Acute Radiation Enteritis

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

We have received "Fast Track" designation from the FDA for SGX201 for radiation enteritis. Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit a New Drug Application ("NDA") for SGX201 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review, which implies an abbreviated review time of six months.

About Acute Radiation Enteritis

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

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

Symptoms will usually resolve within 2-6 weeks after therapy has ceased. Radiation enteritis is often not a self-limited illness, as over 80% of patients who receive abdominal radiation therapy complain of a persistent change in bowel habits. Moreover, acute radiation injury increases the risk of development of chronic radiation enteropathy, and overall 5% to 15% of the patients who receive abdominal or pelvic irradiation will develop chronic radiation enteritis.

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

orBec® – Oral BDP for Treating Chronic Gastrointestinal Graft-versus-Host disease (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 US 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. In September 2012, we received a $300,000 two-year SBIR grant awarded by the NIH to support a Phase 2 study.

orBec® has been awarded orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD.

About Chronic GVHD

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

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

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

LPM™ – Leuprolide for Treating Endometriosis and Prostate Cancer

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

viruses. The reverse micelles also structurally prevent the rapid inactivation of peptides by enzymes in the upper gastrointestinal tract via a non-specific enzyme inhibition by surfactant(s) in the formulation.

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

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

Vaccines/BioDefense Overview

ThermoVax™ – Thermostability Technology

Soligenix's thermostability technology, ThermoVax™, is a novel method of rendering aluminum salt (known colloquially as Alum) adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax™ lies in its potential ability to eliminate the need for cold-chain production, transportation, and storage for Alum adjuvanted vaccines. This would relieve companies of the high costs of producing and maintaining vaccines under refrigerated conditions. The World Health Organization ("WHO") reports that 50% of all vaccines around the world are wasted due to thermostability issues. This is due to the fact that most Alum adjuvanted vaccines need to be maintained at between 2 and 8 degrees Celsius ("C") and even brief excursions from this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. The savings realized from the elimination of cold chain costs and related product losses would in turn significantly increase the profitability of vaccine products. Elimination of the cold chain would also further facilitate the use of these vaccines in the lesser developed parts of the world. On the Vaccines/BioDefense side, ThermoVax™ has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

Initial proof-of-concept preclinical studies with 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 Soligenix's aluminum-adjuvanted ricin toxin vaccine, RiVax™, made under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the ricin A chain, the immunogenic compound of the vaccine. When RiVax™ was kept at 40 degrees C for over three months, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. Confirmatory results have extended the stability to more than three months when the vaccine is kept at 40 degrees C. In contrast, animals that were vaccinated with the liquid RiVax™ vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C.

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

ThermoVax™ is the subject of U.S. patent application number 60/896,429 filed on March 22, 2007 entitled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition." This patent and its corresponding foreign filings are pending and licensed to Soligenix by the University of Colorado and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers

thermostable vaccines for biodefense as well as other potential vaccine indications.

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RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first ricin. With RiVax™, Soligenix is a world leader in ricin toxin vaccine research. The immunogen in RiVax™ induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin. One Phase 1 human clinical trial was completed, and a second trial is currently being conducted. The development of RiVax™ has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to Soligenix and to the University of Texas Southwestern Medical Center ("UTSW") where the vaccine originated. The second clinical trial is being supported by a grant from the FDA's Office of Orphan Products to UTSW. Soligenix and UTSW have collectively received approximately $15 million in grant funding from the NIH for RiVax™. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies anticipated to protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of the study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, PNAS, 105:2268-2273). The second trial, sponsored by UTSW, is currently evaluating a more potent formulation of RiVax™ that contains a conventional adjuvant (salts of aluminum), anticipated to result in higher antibody titers of longer duration in human subjects. This trial is expected to complete in the 2H 2012. Soligenix has adapted the original manufacturing process for the immunogen contained in RiVax™ for large scale manufacturing and is further establishing correlates of the human immune response in non-human primates.

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

About Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigations Bioterror report released in November 2007 entitled Terrorism 2002-2005, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations" (http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf). The Centers for Disease Control ("CDC") has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

VeloThrax™ – Anthrax Vaccine

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

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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.

Initial development work on VeloThrax™ has begun and will be conducted pursuant to Soligenix's $9.4 million NIAID grant enabling development of thermo-stable ricin and anthrax vaccines. 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™, Soligenix believes that it 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.

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 from Infectious Disease Research Institute ("IDRI") which have been demonstrated to enhance potency and reduce the time and number of vaccine doses required to achieve protective titer using a variety of vaccine antigens. This blend of proven yet innovative technologies will provide the Public Health Emergency Medical Countermeasures Enterprise ("PHEMCE") and the Department of Defense ("DoD") with a safe and stable alternative to the existing licensed anthrax vaccine product. Soligenix also proposes to adapt newly developed glassification technology (initially developed under an ongoing NIAID grant to stabilize exceptionally unstable ricin toxin/adjuvant formulations) to enable a thermostable, dried, single vial, pre-formulated adjuvanted rPA vaccine which is suitable for both long term storage and field use without typical cold chain constraints.

About Anthrax

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

OrbeShield™ – Oral BDP for Gastrointestinal Acute Radiation Syndrome (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.

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OrbeShield™ has demonstrated positive preclinical results in a canine GI ARS model which indicate that dogs treated with OrbeShield™ demonstrated statistically significant (p=0.04) improvement in survival with dosing at either 2 hours or 24 hours after exposure to lethal doses of total body irradiation ("TBI") when compared to control dogs. OrbeShield™ appears to significantly mitigate the damage to the GI epithelium caused by exposure to high doses of radiation using a well-established canine model of GI ARS.

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

The application of OrbeShield™ to acute GI ARS originated from other programs for oral BDP and is based on the properties of BDP to act locally in the GI to modulate local inflammation and epithelial cellular apoptosis. Development of OrbeShield™ for GI ARS is a natural extension of Soligenix's radiation enteritis clinical program with SGX201. Killing cancer cells with radiation therapy or chemotherapy must be done in ways that minimize toxicity to the rest of the body, but often leads to an inflammatory condition in the GI tract when administered in that general vicinity. In most radiation scenarios, injury to the hematopoietic (blood) system and GI tract are the main determinants of survival.

Previously, development of OrbeShield™ had been largely supported by a $1 million NIH grant to Soligenix's academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, the Company received a SBIR grant from NIAID of approximately $600,000 to support further preclinical development of OrbeShield™ for the treatment of acute GI ARS.

About GI ARS

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

The Drug Approval Process

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

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

processes, manufacturing and marketing practices established by the FDA must be satisfied.

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

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

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

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase 4 post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the marketing of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes will likely be required to be submitted to the FDA or foreign regulatory authority.

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

For the development of biodefense vaccines, such as RiVax™, the FDA has instituted policies that are expected to result in shorter pathways to market. This potentially includes approval for commercial use utilizing the results of animal efficacy trials, rather than efficacy trials in humans. However, the Company will still have to establish that the vaccine and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the benefit-risk scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the animal rule may raise issues of confidence in the model systems

even if the models have been validated. For many of the biological threats, the animal models are not available and the Company may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the Animal Rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

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Marketing Strategies

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

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

Competition

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

Oral BDP Competition

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

There are 4 compounds currently in development or on 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 (budesonide) is also currently in Phase 3 trials in pediatric Crohn's disease. We believe that SGX203's unique release characteristics, intended to deliver topically active therapy to both the upper and lower gastrointestinal systems, should make SGX203 an attractive alternative to existing therapies for inflammatory diseases of the gastrointestinal tract.

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

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

ThermoVax™ Competition

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

Center have programs designed to advance technologies which may address this need.

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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 the our technologies.

The currently available anthrax vaccine known as BioThrax® (Anthrax Vaccine Adsorbed or AVA) marketed by Emergent BioSolutions, Inc. was developed nearly 50 years ago from a culture filtrate derived from anthrax bacteria. Consequently, it contains a number of different proteins, some of which are believed to potentially contribute to the adverse events that have been reported in the literature (up to 7-8% serious adverse events) and which prompted agencies like the Institute of Medicine to recommend adoption of newer and safer anthrax vaccines. BioThrax® is FDA approved for the prevention of anthrax infection, but requires five doses over a period of eighteen months to achieve protective immunity.

With respect to the development of PA-based vaccines and therapeutics such as 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 disease. Pharmathene and Medarex are collaborating to develop a human antibody to anthrax, known as Valortim™. Bavarian Nordic is developing a multivalent combination vaccine against both anthrax and smallpox.

The only potential competition to RiVax™ is being developed by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the DoD’s lead laboratory for medical research to counter biological threats.

Development of this product, known as RVEc™, is proceeding under a program led by Dr. Len Smith, who has been working for many years to develop a ricin vaccine candidate. Similar to RiVax™, RVEc™ has been shown to be fully protective in mice exposed to lethal doses of ricin toxin by the aerosol route. Further studies, in both rabbits and nonhuman primates, were successfully conducted to evaluate RVEc™'s safety as well as its immunogenicity.

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

Only RxBio and the University of Arkansas have programs specifically for GI ARS. RxBio's Rx100 is a stem cell protectant designed as a single dose (oral or injection) which has shown promise in nonhuman primate studies. Pasireotide, a drug in development by Novartis for Cushing's disease, is being developed at the University of Arkansas to protect the intestine by reducing pancreatic secretions that exacerbate intestinal inflammation.

Patents and Other Proprietary Rights

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

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

We are the exclusive licensee of 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 and European patent EP 1830857 claiming oral BDP in conjunction with a short duration of high-dose prednisone with a rapid taper for the reduction of mortality associated with GVHD and leukemia.

In addition to issued and pending patents, we also have "Orphan Drug" designations for SGX203 in the U.S. for pediatric Crohn's disease, and for orBec® in the U.S. and Europe for GI GVHD. 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 seven year post-approval exclusivity provided by the Orphan Drug Act of 1983.

orBec®/Oral BDP License Agreement

On November 24, 1998, the Company, known at the time as Enteron Pharmaceuticals, Inc. ("Enteron") and George B. McDonald ("Dr. McDonald") entered into an exclusive license agreement for the rights to intellectual property, including know-how, relating to orBec®/oral BDP. The Company has an exclusive license to commercially exploit the covered products worldwide, subject to Dr. McDonald's right to make and use the technology for research purposes and the U.S. Government's right to use the technology for government purposes. In consideration for the license, the

Company has paid to Dr. McDonald a license fee in the amount of $20,000 and is required to (i) reimburse Dr. McDonald for certain out-of-pocket expenses incurred by Dr. McDonald in connection with the patent applications and issued patents, (ii) pay Dr. McDonald a milestone payment in the amount of $300,000; (iii) issue Dr. McDonald shares of common stock equal to 8% of the Company's outstanding common stock as of November 24, 1998, with certain anti-dilution protection, and (iv) pay Dr. McDonald royalty payments equal to 6% of net sales of the covered products.

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

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

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

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

ThermoVax™ License Agreement

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

RiVax™ License Agreement

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

VeloThrax™ License Option Agreement

In December of 2011, we optioned a license to the VeloThrax™ patent from the President and Fellows of Harvard College. VeloThrax™ is the subject of U.S. patent No. 7,037,503, issued on May 2, 2006 and entitled, "Compounds and Methods for the Treatment and Prevention of Bacterial Infection", along with any reissue, renewal, reexamination,

substitution or extension thereof. The PCT application patent was filed in May 2001 and will expire in May 2021 (barring any patent term extensions).

Research and Development Expenditure

We spent approximately $6.3 million and $6.0 million in the years ended December 31, 2011 and 2010, respectively, on research and development. The amounts we spent on research and development per product during the years ended December 31, 2011 and 2010 are set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus.

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Employees

As of October 31, 2012, we had 9 full-time employees, 4 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 is approximately $8,000 per month, or approximately $18.25 per square foot on an annualized basis. This rent increases to approximately $8,310 per month, or approximately $19.00 per square foot on an annualized basis, for the remaining 24 months. Our office space is sufficient to satisfy our current needs.

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.

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

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operation 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 development stage biopharmaceutical company that is focused on developing products to treat serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

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

An outline of our business strategy follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203, in pediatric Crohn's disease;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute radiation enteritis 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 Vaccines/BioDefense programs through grants, contracts and/or procurements;
- Acquire or in-license new clinical-stage compounds for development; and
- Explore other business development and acquisition strategies.

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.

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Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, Research and Development. Based on this consideration, we capitalized payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current 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. We capitalize such 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 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 we incur internal expenses that are related to the grant. Licensing and associated milestone revenues are recorded when earned.

Accounting for Warrants

We considered FASB ASC 815, Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock, and therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. We evaluated the warrants' provisions and determined that they were indexed to our own stock and therefore to be accounted for as an equity instrument for the six months ended June 30, 2012 and 2011.

Stock-Based Compensation

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

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We determine stock-based compensation expense for options, warrants and shares of common stock granted to non-employees in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The option's price is remeasured using the Black-Scholes model at the end of each quarterly reporting period. Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

Material Changes in Results of Operations

Three and Six Months Ended June 30, 2012 Compared to 2011

For the three months ended June 30, 2012, we had a net loss of $979,878 as compared to a net loss of $1,931,317 for the same period in the prior year, representing a decrease in the net loss of $951,439 or 49%. For the six months ended June 30, 2012, we had a net loss of $2,418,633 as compared to a net loss of $3,651,728 for the same period in the prior year, representing a decrease of $1,233,095 or 34%.

For the three and six months ended June 30, 2012, revenues and associated costs related to NIH grants awarded supported development of our thermostable vaccines and orBec®. For the three months ended June 30, 2012, we had revenues of $762,851 as compared to $405,820 for the same period in the prior year, representing an increase of $357,031 or 88%. For the six months ended June 30, 2012, we had revenues of $1,410,269 as compared to $1,213,825 for the same period in the prior year, representing an increase of $196,444 or 16%. The increases in revenues during both periods were a result of increases in NIH grant drawdowns and the associated development work underlying them.

We incurred costs related to those revenues for the three months ended June 30, 2012 and 2011 of $616,330 and $349,511, respectively, representing an increase of $266,819. For the six months ended June 30, 2012, costs related to revenues were $1,172,901 as compared to $903,548 for the same period in the prior year, representing an increase of $269,353, or 30%. These costs relate to payments made to subcontractors in connection with research performed pursuant to the grants. The increases are due to work performed on the NIH grants discussed above.

Our gross profit for the three months ended June 30, 2012 was $146,521 as compared to $56,309 for the same period in 2011, representing an increase of $90,212 or 160%. The increase in gross profit is directly related to the increase in grant revenue. For the six months ended June 30, 2012, gross profit was $237,368 as compared to $310,277 for the same period in the prior year representing a decrease of $72,909 or 23%. The decrease in gross profit is primarily related to the reimbursement in first quarter 2011 of certain salary costs.

Research and development expenses decreased by $1,012,742 to $500,980 for the three months ended June 30, 2012 as compared to $1,513,722 for the same period in 2011. The significant decrease is a result of the discontinuation of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD. For the six months ended June 30, 2012, research and development expenses were $1,377,774 compared to $2,886,526 for the same period in 2011, reflecting a spending decrease of $1,508,752 related to the discontinued Phase 3 orBec® clinical trial.

General and administrative expenses increased by $151,841, or 32%, to $627,218 for the three months ended June 30, 2012, as compared to $475,377 for the same period in 2011. For the six months ended June 30, 2012, general and administrative expenses was $1,282,261 representing an increase of $202,874, or 19% compared to $1,079,387 for the same period in 2011. These increases are primarily attributable to a greater share of allocated salaries to general administrative resulting from a reduction in the number of specifically identifiable research and development

programs.

Year Ended December 31, 2011 Compared to 2010

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

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

We incurred costs related to that revenue in the year ended December 31, 2011 and 2010 of $2,108,228 and $1,638,402, respectively, representing an increase of $469,826, or 29%. These costs primarily relate to payments made to subcontractors in connection with research performed pursuant to grants. The cost changes are due to work performed on the NIH grant revenues discussed above.

Our gross profit for the year ended December 31, 2011 was $5,554,594 as compared to $309,226 for the prior year, representing an increase of $5,245,368. This increase is almost entirely due to the Sigma-Tau Agreement and increase in grant revenues discussed above and a 2011 reimbursement of certain period salary costs which there is no current period cost. Excluding the license revenue associated with the Sigma-Tau Agreement, gross profit would have been $554,594 for the year ended December 31, 2011.

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

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

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

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

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

Business Segments

We maintain two active business segments for the year ended December 31, 2011 and December 31, 2010: Vaccines/BioDefense and BioTherapeutics.

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

result of $5,000,000 received relating to the Sigma-Tau Agreement.

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