

SOLIGENIX, INC.  
Form 424B3  
January 16, 2014

---

---

Filed pursuant to Rule 424(b)3  
Registration Number 333-192908

PROSPECTUS

SOLIGENIX, INC.

3,905,440 SHARES OF COMMON STOCK

This prospectus relates to the offer and sale of up to 3,905,440 shares of our common stock by Lincoln Park Capital Fund, LLC (“Lincoln Park”). Lincoln Park is sometimes referred to in this prospectus as the selling stockholder.

The shares of common stock being offered by the selling stockholder have been or may be issued pursuant to the purchase agreement dated November 18, 2013 that we entered into with Lincoln Park, which we refer to in this prospectus as the “Purchase Agreement.” Please refer to the section of this prospectus entitled “The Lincoln Park Transaction” for a description of the Purchase Agreement and the section entitled “Selling Stockholder” for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

Soligenix, Inc. is not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder. References in this prospectus to the “Company,” “we,” “our,” and “us” refer to Soligenix Inc.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See “Plan of Distribution” for more information about how the selling stockholder may sell the shares of common stock being registered pursuant to this prospectus. The selling stockholder is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See “Plan of Distribution.”

Our common stock is currently quoted on the OTCQB market under the symbol “SNGX”. On January 7, 2014, the last quoted sale price of our common stock as reported on the OTCQB was \$1.90 per share.

Investing in our securities involves significant risks, including those set forth in the “Risk Factors” section of this prospectus beginning on page 5.

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 date of this prospectus is January 16, 2014



Table of Contents

<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	ii
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	5
<u>USE OF PROCEEDS</u>	15
<u>DIVIDENDS</u>	15
<u>DILUTION</u>	16
<u>BUSINESS</u>	17
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	35
<u>MANAGEMENT</u>	41
<u>EXECUTIVE COMPENSATION</u>	45
<u>SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT</u>	49
<u>TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS</u>	51
<u>THE LINCOLN PARK TRANSACTION</u>	52
<u>SELLING STOCKHOLDER</u>	55
<u>PLAN OF DISTRIBUTION</u>	57
<u>DESCRIPTION OF SECURITIES</u>	58
<u>MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	61
<u>DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES</u>	62
<u>EXPERTS</u>	63
<u>LEGAL MATTERS</u>	63
<u>AVAILABLE INFORMATION</u>	63
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1

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

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

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

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

changes in healthcare regulation;

changes in the needs of biodefense procurement agencies;

maintenance and progression of our business strategy;

Table of Contents

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

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

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

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

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

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

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

Table of Contents

PROSPECTUS SUMMARY

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

About Our Company

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

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

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our GI 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. With the recently awarded government contracts from the Biomedical Advanced Research and Development Authority (“BARDA”) and the National Institute of Allergy and Infectious Diseases (“NIAID”), we will attempt to advance the development of OrbeShield™ for the treatment of GI ARS. Additionally, we entered into a global and exclusive channel collaboration with Intrexon Corporation (“Intrexon”) through which we intend to develop and commercialize human monoclonal antibody therapies to treat melioidosis.

An outline of our business strategy follows:

- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Initiate a Phase 2/3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis and treatment of chronic graft –versus host disease (“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;
- Advance the preclinical and manufacturing development of OrbeShield™ as a biodefense medical countermeasure for the treatment of GI ARS;
-

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, an example of which is the recently announced collaboration with Intrexon.



Table of Contents

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

## BioTherapeutic Products

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

## Vaccine Thermostability Platform

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

## BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated; Phase 2 trial planned for the first half of 2015
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2015
OrbeShield™	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943/SGX101	Melioidosis	Pre-clinical

Corporate Information

We were incorporated in Delaware in 1987 under the name Immunotherapeutics Inc. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Table of Contents

## The Offering

On November 18, 2013, we entered into the Purchase Agreement with Lincoln Park, pursuant to which we sold to Lincoln Park 285,714 shares of our common stock for \$600,000 and Lincoln Park has agreed to purchase from us up to an aggregate of \$10,600,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also on November 18, 2013, we entered into a Registration Rights Agreement (the “Registration Rights Agreement”) with Lincoln Park, pursuant to which we have filed with the U.S. Securities and Exchange Commission (the “SEC”) the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended (the “Securities Act”), the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Other than (i) 285,714 shares of our common stock that we have already issued to Lincoln Park for a total purchase price of \$600,000 as an initial purchase under the Purchase Agreement (the “Initial Purchase”), and (ii) 97,656 shares of our common stock that we have already issued to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement, we do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 75,000 shares on any single business day so long as at least one business day has passed since the most recent purchase. We can also increase the amount of our common stock to be purchased under certain circumstances to up to 100,000 shares but not exceeding \$750,000 per purchase plus an additional “accelerated amount” under certain circumstances. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement will be based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount; provided that in no event will such shares be sold to Lincoln Park when our closing sale price is less than \$1.00 per share, subject to adjustment as provided in the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day notice. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As of January 7, 2014, there were 19,626,439 shares of our common stock outstanding, of which 11,751,661 shares were held by non-affiliates, excluding the 383,370 shares that we have already issued to Lincoln Park under the Purchase Agreement. Although the Purchase Agreement provides that we may sell up to \$10,600,000 of our common stock to Lincoln Park, only 3,905,440 shares of our common stock are being offered under this prospectus, which represents (i) 285,714 shares that we issued to Lincoln Park in the Initial Purchase, (ii) 97,656 shares that we issued to Lincoln Park as a commitment fee (iii) an additional 3,400,000 shares which may be issued to Lincoln Park in the future under the Purchase Agreement and (iv) 122,070 shares that we are required to issue proportionally in the future, as an additional commitment fee, if and when we sell shares to Lincoln Park under the Purchase Agreement. The additional commitment shares are issued pro rata as Lincoln Park purchases up to \$10,600,000 of our common stock as directed by us. For example, if we elect, at our sole discretion, to require Lincoln Park to purchase \$100,000 of our stock then we would issue 1,221 shares of the pro rata commitment fee, which is the product of \$100,000 (the amount we have elected to sell) divided by \$10,000,000 (the total amount we can sell Lincoln Park under the Purchase Agreement) multiplied by 122,070 (the total number of pro rata commitment shares), rounded up or down to the nearest whole share. The pro rata commitment shares will only be issued pursuant to this formula as and when we elect at our discretion to sell stock to Lincoln Park. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement. If all of the 3,905,440 shares offered by Lincoln Park under this prospectus were

issued and outstanding as of the date hereof, such shares would represent 16.9% of the total number of shares of our common stock outstanding and 33.2% of the total number of outstanding shares held by non-affiliates, in each case as of the date hereof. If we elect to issue and sell more than the 3,905,440 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Table of Contents

Issuances of our common stock in this offering will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

Securities Offered

Common Stock offered by the selling stockholder 3,905,440 shares consisting of:

97,656 commitment shares issued to Lincoln Park;

3,685,714 shares we may sell to Lincoln Park under the Purchase Agreement, including 285,714 issued in connection with the \$600,000 Initial Purchase; and

122,070 shares that we are required to issue proportionally in the future, as an additional commitment fee, if and when we sell additional shares to Lincoln Park under the Purchase Agreement.

Common stock outstanding prior to the offering 19,626,439 shares, including 285,714 Initial Purchase shares and 97,656 commitment shares previously issued to Lincoln Park under the Purchase Agreement (and included in this offering).

Common stock to be outstanding after giving effect to the total issuance of 3,905,440 shares to Lincoln Park under the Purchase Agreement registered hereunder 23,148,509 shares.

Shares issuable upon exercise of outstanding options and warrants. The total number of shares of our common stock outstanding prior to the offering and to be outstanding after giving effect to the total issuance of 3,905,440 shares to Lincoln Park under the Purchase Agreement registered hereunder, excludes the following:

675,924 shares of common stock reserved for future issuance under our equity incentive plans. As of the date of this prospectus, there were options to purchase 2,151,511 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$2.60 per share; and

8,156,526 shares of common stock issuable upon exercise of outstanding warrants as of the date of this prospectus with a weighted average exercise price of \$2.17 per share.

Use of proceeds

We will not receive any proceeds from the sale of the shares of common stock by Lincoln Park in this offering. However, we may receive up to \$10,600,000 from sales of shares under the Purchase Agreement. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used to further develop our product candidates and for general corporate purposes. See “Use of Proceeds.”

Risk factors

This investment involves a high degree of risk. See “Risk Factors” for a discussion of factors you should consider carefully before making an investment decision.

OTC Markets (OTCQB)  
symbol

SNGX

Table of Contents

RISK FACTORS

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

Risks Related to Our Business

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

We have experienced significant losses since inception and, at September 30, 2013, had an accumulated deficit of approximately \$133.3 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of September 30, 2013, we had approximately \$6.6 million in cash available. Based on our projected budgetary needs and funding from existing grants over the next two years and prior to making any sales to Lincoln Park under the Purchase Agreement, we expect to be able to maintain the current level of our operations into the first quarter of 2015.

We have sufficient funds through our existing biodefense grant facilities from NIAID, a division of the National Institutes of Health (“NIH”) and BARDA, to finance our biodefense projects for the next several years. In September 2013, we entered into contracts with the NIH and BARDA for the development of OrbeShield™ that would provide up to \$32.7 million of funding in the aggregate if options to extend the contracts are exercised by BARDA and the NIH. In September 2009, we received a NIAID grant for approximately \$9.4 million for the development of our biodefense programs and, in July 2012, we received an additional Small Business Innovation and Research (“SBIR”) grant from NIAID for \$600,000. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component, which is approximately 21% above our subcontracted expenses, will finance some fixed costs for direct employees working on the grants and other administrative costs.

Our products are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. From inception through September 2013, we have expended approximately \$50.8 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least \$5 million over the next 12 months 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.





Table of Contents

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

In order to generate revenues and profits, our organization must, along with corporate partners and collaborators, positively research, develop, manufacture and commercialize our technologies or product candidates. Our current product candidates are in various stages of early clinical and pre-clinical development and will require significant further funding, research, development, pre-clinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

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

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

we may encounter problems in clinical trials; or

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

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

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

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

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

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

we are not able to manufacture the product reliably;

others have brought to market similar or superior products; or

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

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

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

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. We estimate that the clinical trials of our product candidates that we have planned will take at least several

years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Favorable results in early studies or trials, if any, may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing, Phase 1 and Phase 2 clinical trials does not ensure that later Phase 2 or Phase 3 clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing. In addition, we, the FDA or other regulatory authorities may suspend clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or the FDA or other regulatory authorities find deficiencies in our submissions or conduct of our trials. For example, our confirmatory Phase 3 clinical trial for orBec® (oral BDP) in the treatment of GI GVHD was stopped on September 15, 2011 at the recommendation of an independent Data Safety Monitoring Board (“DSMB”) as it was highly unlikely to achieve the predetermined end point of efficacy based on the interim results. Although no safety concerns were raised by the DSMB, preliminary findings indicated that there were no significant differences between the orBec® group and placebo group for the primary endpoint or for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, we terminated the development of orBec® for the treatment of acute GI GVHD. Although we hope to obtain FDA approval for oral BDP in similar indications, such as treatment of chronic GI GVHD, treatment of pediatric Crohn's disease, acute radiation enteritis, and GI ARS, there can be no assurances that the FDA will ever approve oral BDP for market launch in any of these indications.

Table of Contents

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, injunctions or other operating restrictions and/or criminal prosecution.

There may be unforeseen challenges in developing our biodefense products.

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

We are and will be dependent on government funding, which is inherently uncertain, in order to progress our biodefense operations.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and other governmental agencies, the viability of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our receipt of government funding is also dependent on our ability to adhere to the terms and provisions of the original grant documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for grants we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business.



## Table of Contents

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

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

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

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

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

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

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

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

and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

## Table of Contents

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

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

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

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

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

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

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

On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that are currently separately billed. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. Moreover, the passage of the Patient Protection and Affordable Care Act in 2010, and efforts to amend or repeal such law, has created significant uncertainty relating to the scope of government regulation of healthcare and related legal and regulatory requirements, which could have an adverse impact on sales of our products.

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



## Table of Contents

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

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

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

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

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

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

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

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

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

## Table of Contents

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

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

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

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

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

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

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

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



Table of Contents

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

During recent months, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment and the partial government shutdown due to delays in increasing the U.S. debt limit in October 2013. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by current and future economic conditions. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows.

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

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

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

Risks Related to Our Common Stock

Our common stock price is highly volatile.

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

announcements by us or others of results of pre-clinical testing and clinical trials;

announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;

our quarterly operating results and performance;

developments or disputes concerning patents or other proprietary rights;

acquisitions;

litigation and government proceedings;

adverse legislation;  
changes in government regulations;  
our available working capital;  
economic and other external factors; and  
general market conditions.

## Table of Contents

Since January 1, 2012, the closing stock price (split adjusted) has fluctuated between a high of \$2.39 per share to a low of \$0.23 per share. As of January 7, 2014, our common stock closed at \$1.90 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of our common stock, as well as potential sale of common stock by the holders of warrants and options, could have an adverse effect on the market price of our shares.

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

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

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

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

As of September 30, 2013, we had a number of agreements or obligations that may result in dilution to investors. These include:

warrants to purchase a total of approximately 8,152,776 shares of our common stock at a current weighted average exercise price of approximately \$2.17; and

options to purchase approximately 1,915,324 shares of our common stock at a current weighted average exercise price of approximately \$2.58.

We also established an incentive compensation plan for our management, employees and consultants. We have granted, and expect to grant in the future, options to purchase shares of our common stock to our directors, employees and consultants. To the extent that warrants or options are exercised, our stockholders will experience dilution and our stock price may decrease.

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



Table of Contents

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

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

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

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

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

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

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

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



## Table of Contents

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On November 18, 2013, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to \$10,600,000 of our common stock. Concurrently with the execution of the Purchase Agreement, we issued 97,656 shares of our common stock to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The purchase shares that may be sold pursuant to the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the closing sale price of our common stock is below \$1.00 per share, subject to adjustment as set forth in the Purchase Agreement. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

## USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will not receive any proceeds upon the sale of shares by Lincoln Park in this offering. However, we may receive gross proceeds of up to \$10,600,000 under the Purchase Agreement with Lincoln Park over an approximately 36-month period, assuming that we sell the full amount of our common stock that we have the right, but not the obligation, to sell to Lincoln Park under that agreement. See “Plan of Distribution” elsewhere in this prospectus for more information.

We will use the net proceeds from this offering to further develop our products and product candidates and for working capital and other general corporate purposes. We will have broad discretion in determining how we will allocate the proceeds from any sales to Lincoln Park.

## DIVIDENDS

We have never declared nor paid any cash dividends, and currently intend to retain all our cash and any earnings for use in our business and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our consolidated financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.



Table of Contents

## DILUTION

Investors who purchase our common stock will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the number of outstanding shares of our common stock. As of September 30, 2013, we had a net tangible book value (deficit) of \$(4,284,757), or approximately \$(0.22) per share of common stock.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of common stock in this offering, assuming a purchase price of \$1.00 per share, which is the minimum purchase price at which shares can be sold under the Purchase Agreement, and the pro forma as adjusted net tangible book value per share of common stock immediately after the completion of this offering. Therefore, after giving effect to our assumed receipt of \$3,970,000 in estimated net proceeds from the issuance of 3,824,874 additional shares of common stock under the Purchase Agreement and registered in this offering (assuming a purchase price of \$1.00 per share for 3,400,000 shares, the issuance of 139,160 commitment shares for no additional cash consideration, the issuance of 285,714 shares for \$600,000, offering expenses of \$30,000, and assuming all such sales and issuances were made on September 30, 2013), our pro forma as adjusted net tangible book value (deficit) as of September 30, 2013 would have been approximately \$(314,757), or \$(0.01) per share. This would represent an immediate increase in the net tangible book value of \$0.21 per share to existing shareholders attributable to this offering. The following table illustrates this per share dilution:

Assumed public offering price per share of common stock (minimum allowed price)		\$1.00
Net tangible book value (deficit) per share as of September 30, 2013	\$(0.22	)
Increase in as adjusted net tangible book value per share attributable to this offering	0.21	
Pro forma net tangible book value (deficit) per share after this offering		(0.01
Dilution per share to new investors		\$1.01

To the extent that we sell more or less than \$4,000,000 worth of shares under the Purchase Agreement, or to the extent that some or all sales are made at prices in excess of the minimum allowable purchase price of \$1.00 per share, then the dilution reflected in the table above will differ. The above table is based on 19,152,630 shares of our common stock outstanding as of September 30, 2013, adjusted for the assumed sale of \$3,400,000 in shares to Lincoln Park under the Purchase Agreement at the assumed minimum purchase price described above, the issuance of 41,504 commitment shares for no additional cash consideration, and the issuance of 285,714 shares for \$600,000.

To the extent that we issue additional shares of common stock in the future, there may be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

Table of Contents

BUSINESS

Overview

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

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

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome (“GI ARS”) therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding. With the recently awarded government contracts from the Biomedical Advanced Research and Development Authority (“BARDA”) and the National Institute of Allergy and Infectious Diseases (“NIAID”), we will attempt to advance the development of OrbeShield™ for the treatment of GI ARS. Additionally, we entered into a global and exclusive channel collaboration with Intrexon Corporation (“Intrexon”) through which we intend to develop and commercialize human monoclonal antibody therapies to treat melioidosis.

An outline of our business strategy follows:

- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Initiate a Phase 2/3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis and treatment of chronic graft –versus host disease (“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;
- Advance the preclinical and manufacturing development of OrbeShield™ as a biodefense medical countermeasure for the treatment of GI ARS;
- 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, an example of which is the recently announced collaboration with Intrexon Corporation.

We were incorporated in Delaware in 1987. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Table of Contents

## Our Products in Development

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

## BioTherapeutic Products

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

## Vaccine Thermostability Platform

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

## BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated; Phase 2 trial planned for the first half of 2015
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2015
OrbeShield™	Therapeutic against GI ARS	Pre-clinical program initiated;



SGX943/SGX101

Melioidosis

Pre-clinical

18

---

## Table of Contents

### BioTherapeutics Overview

#### SGX94

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

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

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

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

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

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

SGX942 is poised to start a Phase 2 clinical study in oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA in the first half of 2013. Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast Track designation is designed to

facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit a New Drug Application (“NDA”) for SGX942 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review, which implies an abbreviated review time of six months.

## Table of Contents

### About Oral Mucositis

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

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

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

### Oral BDP

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

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

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

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

SGX203 –for Treating Pediatric Crohn’s Disease

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

## Table of Contents

### About Pediatric Crohn's Disease

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

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

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

### SGX201 –for Preventing Acute Radiation Enteritis

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

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

### About Acute Radiation Enteritis

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

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

## Table of Contents

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

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

### orBec® –for Treating Chronic GI GVHD

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

### About Chronic GVHD

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

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

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

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

### Vaccines/BioDefense Overview

### ThermoVax™ – Thermostability Technology



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

## Table of Contents

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

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

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

### RiVax™ – Ricin Toxin Vaccine

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

large scale manufacturing and are further establishing correlates of the human immune response in non-human primates.

## Table of Contents

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

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

### About Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigations Bioterror report released in November 2007 titled Terrorism 2002-2005, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations" ([http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02\\_05.pdf](http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf)). In recent years, Al Qaeda branches in Yemen and the Arabian Peninsula have threatened the use of ricin toxin to poison food and water supplies and in connection with explosive devices. Domestically, the threat from ricin remains a concern for security agencies. As recently as April 2013, letters addressed to the President, a U.S. Senator and a judge tested positive for ricin.

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

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

### VeloThrax™ – Anthrax Vaccine

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

pathways, which is consistent with known properties of the molecule.

## Table of Contents

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

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

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

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

### About Anthrax

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

### OrbeShield™ –for Treating GI ARS

OrbeShield™ (an oral immediate and delayed release formulation of the topically active corticosteroid BDP) is being developed for the treatment of GI ARS. Corticosteroids are the best understood and most widely used class of

anti-inflammatory drugs. BDP is a corticosteroid with predominantly topical activity that is approved for use in asthma, psoriasis and allergic rhinitis.

## Table of Contents

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

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. This is the same type of toxicity that occurs in Soligenix’s acute radiation enteritis clinical program with SGX201. As a result, there is a dual avenue of development for Soligenix, and OrbeShield™ is potentially a “dual use” compound, a desirable characteristic which is a specific priority of BARDA for ARS and other medical countermeasure indications. In September 2013, we received two government contracts from BARDA and NIAID, for the advanced preclinical and manufacturing development of OrbeShield™ leading to FDA approval to treat GI ARS. The BARDA contract contains a two year base period with two contract options, exercisable by BARDA, for a total of five years and up to \$26.3 million. The NIAID contract consists of a one year base period and two contract options, exercisable by NIAID, for a total of three years and up to \$6.4 million.

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

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

## About GI ARS

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

## SGX943/SGX101– for Treating Melioidosis

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



treatment with the few antibiotics that do work. Thus, SGX943 may represent a much-needed novel and additive therapy for melioidosis.

## Table of Contents

SGX 101 is the research name for the human monoclonal antibody therapy for the treatment of melioidosis based upon Intrexon's advanced human antibody discovery, isolation, and production technologies. As this research and development program progresses, grant funding will be pursued.

### About Melioidosis

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

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

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

### The Drug Approval Process

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

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

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

Clinical trials for INDs are normally done in three phases, although the phases may overlap. Phase 1 trials are smaller trials concerned primarily with metabolism and pharmacologic actions of the drug and with the safety of the product. Phase 2 trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase 3 trials are expanded clinical trials intended to gather additional information on safety and effectiveness needed to clarify the product's

benefit-risk relationship and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4, or post-marketing, studies to be conducted.

## Table of Contents

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

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

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

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

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

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

## Table of Contents

### Marketing Strategies

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

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

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

### Competition

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

#### SGX94/942 Competition

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

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

#### Oral BDP Competition

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

## Table of Contents

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

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

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

### ThermoVax™ Competition

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

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

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

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

### Vaccines/BioDefense Competition



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

## Table of Contents

The currently available anthrax vaccine known as BioThrax® (Anthrax Vaccine Adsorbed or AVA) marketed by Emergent BioSolutions, Inc. was developed nearly 50 years ago from a culture filtrate derived from anthrax bacteria. Consequently, it contains a number of different proteins, some of which are believed to potentially contribute to the adverse events that have been reported in the literature (up to 7-8% serious adverse events) and which prompted agencies like the Institute of Medicine to recommend adoption of newer and safer anthrax vaccines. BioThrax® is FDA approved for the prevention of anthrax infection, but requires five doses over a period of 18 months to achieve protective immunity.

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

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

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

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

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

## Patents and Other Proprietary Rights

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

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

## Table of Contents

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

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

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

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

### Oral BDP License Agreement

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

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

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

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



## Table of Contents

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

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

### SGX 94 License Agreements

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

### ThermoVax™ License Agreement

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

### RiVax™ License Agreement

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

### VeloThrax™ License Option Agreement

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

## Table of Contents

### Intrexon Exclusive Channel Collaboration Agreement

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

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

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

### Research and Development Expenditure

We spent approximately \$4.8 million, \$2.6 million and \$6.3 million in the years ended December 31, 2013, 2012 and 2011, respectively, on research and development. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations” beginning on page 34 of this prospectus for more information on the amounts we spent on research and development per product during the years ended December 31, 2012 and 2011, respectively.

### Employees

As of December 31, 2013, we had 17 full-time employees, seven of whom are MDs/DOs/PhDs.

### Properties

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

### Legal Proceedings

From time to time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable.



Table of Contents

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

The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operations and financial condition. You should read this analysis in conjunction with our audited consolidated financial statements and related notes and our unaudited consolidated interim financial statements and their notes. This discussion and analysis contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions, and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this prospectus, which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Risk Factors" in this prospectus. See "Forward-Looking Statements."

Our Business Overview

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

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

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome ("GI ARS") therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding. With the recently awarded government contracts from the Biomedical Advanced Research and Development Authority ("BARDA") and the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of OrbeShield™ for the treatment of GI ARS. Additionally, we entered into a global and exclusive channel collaboration with Intrexon Corporation ("Intrexon") through which we intend to develop and commercialize human monoclonal antibody therapies to treat melioidosis.

An outline of our business strategy follows:

- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Initiate a Phase 2/3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn's disease;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis and treatment of chronic graft-versus host disease ("GVHD");
- Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology known as ThermoVax™ to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

- Advance the preclinical and manufacturing development of OrbeShield™ as a biodefense medical countermeasure for the treatment of GI ARS;
- 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, an example of which is the recently announced collaboration with Intrexon.

## Table of Contents

### Critical Accounting Policies

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

### Intangible Assets

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

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

### Research and Development Costs

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

### Revenue Recognition

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

### 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").

## Table of Contents

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

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

## Results of Operations

### Three and Nine Months Ended September 30, 2013 Compared to September 30, 2012

For the three months ended September 30, 2013, we had a net loss of \$6,559,856 as compared to a net loss of \$758,966 for the same period in the prior year, representing an increase in the net loss of \$5,800,890. For the nine months ended September 30, 2013, we had a net loss of \$11,052,427 as compared to a net loss of \$3,177,599 for the same period in the prior year, representing an increase of \$7,874,828. Included in the net loss for the three months and nine months ended September 30, 2013, is a non-cash charge of \$4,699,846 and \$5,349,422, respectively, which represents the change in the fair value of the warrant liability related to warrants issued in connection with our recent registered public offering.

For the three and nine months ended September 30, 2013, revenues and associated costs related to NIH grants awarded which supported development of our thermostable vaccines and orBec®. For the three months ended September 30, 2013, we had revenues of \$312,491 as compared to \$931,627 for the same period in the prior year, representing a decrease of \$619,136 or 66%. For the nine months ended September 30, 2013, we had revenues of \$1,845,123 as compared to \$2,341,896 for the same period in the prior year, representing a decrease of \$496,773 or 21%. The changes in revenues during both periods were a result of timing of grant activity impacting our NIH grant drawdowns and the associated development work underlying them.

We incurred costs related to those revenues for the three months ended September 30, 2013 and 2012 of \$245,864 and \$761,628, respectively, representing a decrease of \$515,764, or 68%. For the nine months ended September 30, 2013, costs related to revenues were \$1,517,469 as compared to \$1,934,529 for the same period in the prior year, representing a decrease of \$417,060, or 22%. These costs relate to payments made to subcontractors in connection with research performed pursuant to the grants. The fluctuations are due to the development activity performed on the NIH grants discussed above.

Our gross profit for the three months ended September 30, 2013 was \$66,627 as compared to \$169,999 for the same period in 2012, representing a decrease of \$103,372, or 61%. The decrease in gross profit is directly related to the decrease in grant revenue. For the nine months ended September 30, 2013, gross profit was \$327,654 as compared to \$407,367 for the same period in the prior year representing a decrease of \$79,713 or 20%. The decrease in gross profit is attributable to our decrease in grant revenue.

Research and development expenses increased by \$845,221, or 228%, to \$1,216,559 for the three months ended September 30, 2013 as compared to \$371,338 for the same period in 2012. For the nine months ended September 30,

2013, research and development expenses were \$4,113,686 compared to \$1,749,112 for the same period in 2012, reflecting an increase of \$2,364,574 or 135%. The increase of \$845,221 for the three months September 30, 2013, was a result of preparation for initiating clinical trials with SGX942 for the treatment of oral mucositis and SGX203 for the treatment of pediatric Crohn's disease. For the nine months September 30, 2013, the significant increase of \$2,364,574 was a result of the exclusive channel collaboration agreement entered into with Intrexon Corporation under which we issued common stock with a value of \$1,500,000 and costs related to the preparation for initiating clinical trials with SGX942 and SGX203.

Table of Contents

Year Ended December 31, 2012 Compared to 2011

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

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

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

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

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

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

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

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

## Table of Contents

### Business Segments

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

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

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

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

### Financial Condition and Liquidity

#### Cash and Working Capital

As of September 30, 2013, we had cash and cash equivalents of \$6,582,556 as compared to \$3,356,380 as of December 31, 2012, representing an increase of \$3,226,176 or 96%. As of September 30, 2013, we had working capital of \$5,672,312, which excludes a non cash warrant liability of \$9,975,899, as compared to working capital of \$2,682,383 as of December 31, 2012, representing an increase of \$2,989,929 or 111%. The increase in cash and working capital was primarily the result of net proceeds of \$6,216,762 received from our registered public offering partially offset by \$3,164,333 of cash used in operating activities during the nine month period ended September 30, 2013.

Based on cash on hand, our current rate of cash outflows, proceeds from our grant-funded programs, and expected proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that our cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the first quarter 2015.

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

- We have approximately \$34.6 million in active grant funding available to support our associated research programs into 2018. We plan to submit additional grant applications for further support of our development programs with various funding agencies.



- We have continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expect to continue to do so for the foreseeable future.
  - We will pursue the sale of Net Operating Losses (“NOLs”) in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$521,458 in proceeds from the sale of NJ NOL in 2012, we expect to participate in this expanded program during 2013 and beyond as the program is available.
- We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Table of Contents

## Reverse Stock Split

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

## Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately \$12.4 million before any grant reimbursements, of which \$4.9 million relates to the BioTherapeutics business and \$7.5 million relates to the Vaccines/BioDefense business. We anticipate contract and grant revenues in the next 12 months of approximately \$9.1 million to primarily offset research and development expenses in the Vaccines/BioDefense business segment.

The table below details our costs for research and development by program and amounts reimbursed under grants for the nine months ended September 30:

	2013	2012
Research & Development Expenses		
Oral BDP	\$ 1,002,987	\$ 616,532
RiVax™ and ThermoVax™ Vaccines	1,201,699	1,035,878
SGX 94	142,175	-
SGX 943/SGX101	1,500,000	-
Other	266,825	96,702
Total	\$ 4,113,686	\$ 1,749,112
Reimbursed under NIH Grants		
Oral BDP	\$ 139,329	\$ 162,060
RiVax™ and thermostable vaccines	1,378,140	1,772,469
Total	1,517,469	1,934,529
Grand Total	\$ 5,631,155	\$ 3,683,641

## Contractual Obligations

We have commitments of approximately \$356,300 as of September 30, 2013 relating to several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization milestones will occur.

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



Table of Contents

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

As a result of the above agreements, we have future contractual obligations as of September 30, 2013 over the next five years as follows:

Year	Research and Development	Property and Other Leases	Total
2013	\$ 31,300	\$ 26,400	\$ 57,700
2014	100,000	101,200	201,200
2015	75,000	24,900	99,900
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	\$ 356,300	\$ 152,500	\$ 508,800

## MANAGEMENT

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

Name	Age	Position
Christopher J. Schaber, PhD	47	Chairman of the Board, Chief Executive Officer and President
Keith L. Brownlie, CPA	61	Director
Marco M. Brughera, DVM	58	Director
Gregg A. Lapointe, CPA	55	Director
Robert J. Rubin, MD	67	Director
Jerome Zeldis, MD, PhD	63	Director
Robert N. Brey, PhD	63	Chief Scientific Officer and Senior Vice President
Richard Straube, MD	62	Senior Vice President and Chief Medical Officer
Joseph M. Warusz, CPA	57	Vice President of Finance, Acting Chief Financial Officer and Corporate Secretary

Christopher J. Schaber, PhD has over 24 years of experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been our President and Chief Executive Officer and a director since August 2006. He was appointed Chairman of the Board on October 8, 2009. He also serves on the board of directors of the Biotechnology Council of New Jersey (“BioNJ”) since January 2009, and is a member of the corporate councils of both the National Organization for Rare Diseases (“NORD”) and the American Society for Blood and Marrow Transplantation (“ASBMT”) since October 2009 and July 2009, respectively. Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, pre-clinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. During his tenure at Discovery Laboratories, Inc., Dr. Schaber played a

significant role in raising over \$150 million through both public offerings and private placements. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his BA degree from Western Maryland College, his MS degree in Pharmaceutics from Temple University School of Pharmacy and his PhD degree in Pharmaceutical Sciences from the Union Graduate School. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as an executive senior officer with our company and Discovery Laboratories, Inc., and as a member of the board of directors of BioNJ; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

Table of Contents

Keith L. Brownlie, CPA has been a director since June 2011. Mr. Brownlie currently serves on the Board of Directors of RXi Pharmaceuticals Corporation, a publicly traded biotechnology company involved in the research and development of RNAi products for the diagnosis, prevention and treatment of human diseases, a position he has held since June 2012. In July 2013, Mr. Brownlie was appointed to the Board of Cancer Genetics, Inc., a publicly traded, early stage diagnostics company. Mr. Brownlie served as a member of the Board of Directors of Epicept Corporation, a publicly traded, specialty pharmaceutical company focused on the clinical development and commercialization of pharmaceutical products for the treatment of cancer and pain, from April 2011 to August 2013 when Epicept Corporation merged with Immune Pharmaceuticals, Inc. From 1974 to 2010, Mr. Brownlie worked with the accounting firm of Ernst & Young LLP where he served as audit partner for numerous public companies and was the Life Sciences Industry Leader for the New York metro area where he was involved with over 100 public and private financings and M&A transactions. Mr. Brownlie received a BS in Accounting from Lehigh University and is a Certified Public Accountant in the state of New Jersey. Mr. Brownlie co-founded the New Jersey Entrepreneur of the Year Program and was Vice President and Trustee of the New Jersey Society of CPAs. In addition, he served as accounting advisor to the board of the Biotechnology Council of New Jersey. Mr. Brownlie was selected to serve as a member of our Board of Directors because of his vast experience as an audit partner for numerous public companies and as a director of a publicly traded specialty pharmaceutical and biotechnology companies.

Marco M. Brughera, D.V.M. has been a director since December 2013. Dr. Brughera currently serves as the Global Head of the Rare Disease Franchise for Sigma-Tau S.p.A., a position he has held since October 2012. He also currently serves on the Board of Directors of Gentium S.p.A., a publicly traded biopharmaceutical company, a position he has held since December 2011. From January 2011 through October 2012, Dr. Brughera held several other positions with the Sigma-Tau Group, including Corporate Research and Development Managing Director of Sigma-Tau S.p.A., President of Sigma-Tau Research Switzerland S.A. and a board member of Sigma-Tau Pharmaceuticals, Inc. and of Sigma Tau Rare Diseases S.A. From 2004 to 2010, Dr. Brughera served as the Vice President of Preclinical Development at Nerviano Medical Science S.r.l., a pharmaceutical oncology-focused integrated discovery and development company. He also served as the Managing Director at Accelerera S.r.l., an independent contract research organization affiliated with Nerviano Medical Science S.r.l. From 1999 to 2004, Dr. Brughera held several senior level positions in the areas of discovery and development toxicology with Pharmacia Corporation and Pfizer, Inc. Prior to 1999, he held various positions at Pharmacia & Upjohn Company, Inc. and Farmitalia Carlo Erba S.p.A., an Italian pharmaceutical company. Dr. Brughera earned his degree in veterinary medicine from the University of Milan and is a European Registered Toxicologist.

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



Table of Contents

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

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

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



Richard Straube, MD has been with our company since January 2014 and is currently our Senior Vice President and Chief Medical Officer. Dr. Straube is a board-certified pediatrician with 35 years' experience in both academia and industry, including clinical research experience in host-response modulation. Prior to joining the Company, Dr. Straube served from 1988 to 1993 in various capacities, including most recently as Senior Director, Infectious Diseases and Immunology, Clinical Research, for Centocor, Inc., a privately-held biopharmaceutical company focused on developing monoclonal antibody-based diagnostics. While at Centocor, Inc., Dr. Straube was responsible for the initial anti-cytokine and anti-endotoxin programs targeted at ameliorating inappropriate host responses to infectious and immunologic challenges. Programs that he managed at Centocor, Inc. include assessments of immunomodulation using monoclonal removal of inciting molecular triggers, removal of internal immune-messengers, augmentation of normal host defenses, and maintenance of normal sub-cellular function in the face of injury. From 1993 to 1995, Dr. Straube was Director of Medical Affairs at T-cell Sciences, Inc., a privately-held biotechnology company. From 1995 to 1997, he was Director of Clinical Investigations of the Pharmaceutical Products Division of Ohmeda Corp., a privately-held biopharmaceutical company. He served from 1998 to 2007 as Executive Vice President of Research and Development and Chief Scientific Officer at INO Therapeutics LLC, a privately-held biotherapeutics company, where he was responsible for the clinical trials and subsequent approval of inhaled nitric oxide for the treatment of persistent pulmonary hypertension of the newborn. From 2007 to 2009, Dr. Straube was the Chief Medical Officer at Critical Biologics Corporation, a privately-held biotechnology company. From 2009 until joining the Company, he was Chief Medical Officer of Stealth Peptides Incorporated, a privately-held, clinical stage, biopharmaceutical company. Dr. Straube received his medical degree and residency training at the University of Chicago, completed a joint adult and pediatrician infectious diseases fellowship at the University of California, San Diego ("UCSD"), and as a Milbank Scholar completed training in clinical trial design at the London School of Hygiene and Tropical Medicine. While on the faculty at the UCSD Medical Center, his research focused on interventional studies for serious viral infections.

Joseph M. Warusz, CPA has more than 30 years of financial management experience in public and private life science companies as well as large pharma. Prior to joining Soligenix on June 1, 2011 as Vice President of Administration and Controller, he held senior financial positions with Amicus Therapeutics, Inc., Orchid Cellmark, Inc., and NexMed, Inc., as well as consulting assignments at Ardea BioSciences, Inc., and NovaDel Pharma, Inc., all R&D-focused companies in the biotechnology and specialty pharmaceuticals arenas. On February 15, 2012, he was appointed Acting Chief Financial Officer of our company. Prior to 1998, Mr. Warusz also held management positions in financial analysis, accounting, reporting and auditing at Bristol-Myers Squibb and Peat Marwick Main & Company. He received his BS in accounting and MBA in finance at Drexel University and is a Certified Public Accountant.

## Table of Contents

### Board Leadership Structure and Independence

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

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

Although we believes that the combination of the Chairman and Chief Executive Officer roles is appropriate under the current circumstances, our corporate governance guidelines do not establish this approach as a policy, and our Board of Directors may determine that it is more appropriate to separate the roles in the future.

### Code of Ethics

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

### Diversity Considerations in Identifying Director Nominees

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

### Audit Committee Financial Expert

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

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

Table of Contents

## EXECUTIVE COMPENSATION

## Summary Compensation

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2013 to our Chief Executive Officer and each of the two other most highly compensated executive officers during 2013 (collectively, the “Named Executive Officers”).

## Summary Compensation

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber (1)	CEO & President	2013	\$ 402,000	\$ 239,000	\$ 475,100	\$ 33,896	\$ 1,149,996
		2012	\$ 390,000	-	-	\$ 38,006	\$ 428,006
Robert N. Brey (2)	CSO & Senior VP	2013	\$ 214,000	\$ 30,000	\$ 97,450	\$ 20,978	\$ 362,428
		2012	\$ 210,000	-	-	\$ 23,375	\$ 233,375
Joseph M. Warusz (3)	VP & Acting CFO	2013	\$ 186,000	\$ 90,000	\$ 205,850	\$ 32,641	\$ 514,491
		2012	\$ 180,000	-	-	\$ 38,006	\$ 218,006

- 
- 1 Dr. Schaber deferred payment of his 2013 annual bonus of \$130,000 until January 15, 2014. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us. In 2012, no bonus was awarded or option awards issued. On December 5, 2012, the Board granted Dr. Schaber an option to purchase 130,000 shares of common stock at a price of \$0.68 per share, subject to stockholder approval of an amendment to increase in the number of shares available for issuance under our 2005 Equity Incentive Plan under which the stock option was granted. Our stockholders approved the amendment to the 2005 Equity Incentive Plan on September 25, 2013. The stock option vested on September 25, 2013 as to 32,500 shares and vests as to the remainder at a rate of 8,125 shares on each three (3) month anniversary of the grant date. On December 5, 2013, the Board granted Dr. Schaber an option to purchase 100,000 shares of common stock at a price of \$2.01 per share. The stock option vested on December 5, 2013 as to 25,000 shares and vests as to the remainder at a rate of 6,250 shares on each three (3) month anniversary of the grant date.
  - 2 Dr. Brey deferred payment of his 2013 annual bonus of \$10,000 until January 15, 2014. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us. In 2012, no bonus was awarded or option awards issued. On December 5, 2012, the Board granted Dr. Brey an option to purchase 35,000 shares of common stock at a price of \$0.68 per share, subject to stockholder approval of an amendment to increase in the number of shares available for issuance the 2005 Equity Incentive Plan under which the stock option was granted. Our stockholders approved the amendment to the 2005 Equity Incentive Plan on September 25, 2013. The stock option vested on September 25, 2013 as to 8,750 shares and vests as to the remainder at a rate of 2,188 shares on each three (3) month anniversary of the grant date. On December 5, 2013, the Board granted Dr. Brey an option to purchase 10,000 shares of common stock at a price of \$2.01 per share. The stock option vested on December 5, 2013 as to 2,500 shares and vests as to the remainder at a rate of 625 shares on each three (3) month anniversary of the grant

date.

- 3 Mr. Warusz deferred payment of his 2013 annual bonus of \$50,000 until January 15, 2014. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by us. In 2012, no bonus was awarded or option awards issued. On December 5, 2012, the Board granted Mr. Warusz an option to purchase 55,000 shares of common stock at a price of \$0.68 per share, subject to stockholder approval of an amendment to increase in the number of shares available for issuance the 2005 Equity Incentive Plan under which the stock option was granted. Our stockholders approved the amendment to the 2005 Equity Incentive Plan on September 25, 2013. The stock option vested on September 25, 2013 as to 13,750 shares and vests as to the remainder at a rate of 3,438 shares on each three (3) month anniversary of the grant date. On December 5, 2013, the Board granted Mr. Warusz an option to purchase 45,000 shares of common stock at a price of \$2.01 per share. The stock option vested on December 5, 2013 as to 11,250 shares and vests as to the remainder at a rate of 2,812.5 shares on each three (3) month anniversary of the grant date.

Table of Contents

Employment and Severance Agreements

In August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, PhD. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of \$300,000 per year and a minimum annual bonus of \$100,000. This employment agreement was renewed in December 27, 2007 for an additional term of three years. We agreed to issue him options to purchase 125,000 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without “Just Cause” as defined by this agreement, we would pay Dr. Schaber nine months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependents. No unvested options shall vest beyond the termination date. Dr. Schaber’s monetary compensation (base salary of \$300,000 and bonus of \$100,000) remained unchanged from 2006 with the 2007 renewal. Upon a change in control of our company due to merger or acquisition, all of Dr. Schaber’s options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during the term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber’s immediate family. This agreement automatically renewed in December 2010 for an additional term of three years.

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

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

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

Table of Contents

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

## Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2013. We have never issued Stock Appreciation Rights.

Name	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable			
Christopher J. Schaber	125,000	-	-	\$ 5.40	8/28/2016
	45,000	-	-	\$ 9.40	8/9/2017
	140,000	-	-	\$ 1.20	12/17/2018
	110,000	-	-	\$ 4.64	6/30/2020
	90,000	30,000	30,000	\$ 0.64	11/30/2021
	65,000	65,000	65,000	\$ 0.68	12/4/2022
Robert N. Brey	25,000	75,000	75,000	\$ 1.99	12/4/2023
	30,000	-	-	\$ 6.60	5/10/2016
	10,000	-	-	\$ 9.40	8/9/2017
	40,000	-	-	\$ 1.20	12/17/2018
	42,500	-	-	\$ 4.64	6/30/2020
	24,066	10,934	10,934	\$ 0.64	11/30/2021
	17,502	17,498	17,498	\$ 0.68	12/4/2022
2,500	7,500	7,500	\$ 1.99	12,4,2023	
Joseph M. Warusz	35,000	5,000	5,000	\$ 4.10	5/30/2021
	22,500	7,500	7,500	\$ 0.64	11/30/2021
	27,502	27,498	27,498	\$ 0.68	12/4/2022
	11,250	33,750	33,750	\$ 1.99	12/4/2023

Table of Contents

## Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2013.

Name	Fees Earned		Total
	Paid in Cash (1)	Option Awards (2)	
Keith Brownlie	\$ 60,000	\$ 30,000	\$ 90,000
Marco M. Brughera	\$ 8,750	\$ 30,150	\$ 38,900
Gregg A. Lapointe	\$ 47,320	\$ 30,000	\$ 77,320
Robert J. Rubin	\$ 52,500	\$ 30,000	\$ 82,500
Jerry Zeldis	\$ 50,000	\$ 30,000	\$ 80,000

- 1 Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors. Each independent director who is not a full-time employee is paid \$35,000 annually, on a prorated basis, for their service on our Board of Directors, the chairman of our Audit Committee is paid \$15,000 annually, on a prorated basis, and the chairmen of our Compensation and Nominating Committees will be paid \$10,000 annually, on a prorated basis. Additionally, Audit Committee members are paid \$7,500 annually and Compensation and Nominating Committee members are paid \$5,000 annually. This compensation is paid quarterly.
- 2 We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of our Board of Directors or its committees who are not full-time employees receive an initial grant of fully vested options to purchase 15,000 shares of common stock. Upon re-election to the Board, each Board member will receive an option to purchase up to 25,000 shares of common stock (not to exceed a value of \$30,000 in cash based upon the fair market value of the common stock on the date that such options are granted), which vest at the rate of 25% per quarter, commencing with the first quarter after each annual meeting of stockholders.

## Stock Ownership Policy

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

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





Table of Contents

## SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT

The table below provides information regarding the beneficial ownership of the common stock as of the date of this prospectus, of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of the date of this prospectus are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 19,626,439 shares of common stock outstanding as of the date of this prospectus.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Class
Randall J. Kirk (1)	6,867,816	31.04%
Paolo Cavazza (2)	3,379,950	16.84%
Christopher J. Schaber (3)	690,675	3.41%
Robert N. Brey (4)	173,444	*
Gregg A. Lapointe (5)	142,205	*
Jerry Zeldis (6)	88,304	*
Richard Straube (7)	25,000	*
Robert J. Rubin (8)	83,237	*
Keith Brownlie (9)	79,971	*
Joseph Warusz (10)	106,878	*
Marco Brughera (11)	15,000	*
All directors and executive officers as a group (8 persons)	1,404,714	6.74%

(1) On June 26, 2013, Randal J. Kirk, on his own behalf and on behalf of Third Security, LLC, NYM VII Holdings I, LLC and Intrexon Corporation, filed Amendment No. 1 to Schedule 13D with the Securities and Exchange Commission (the "SEC"), which amends the Schedule 13D filed May 9, 2013 with the SEC (as amended, "Schedule 13D"). The Schedule 13D states that Mr. Kirk is Senior Managing Director of, and controls, Third Security, LLC, which is the Manager of an affiliate that manages NRM VII Holdings I, LLC, and that Mr. Kirk serves as the Chairman and Chief Executive Officer of Intrexon Corporation. The Schedule 13D indicates that (a) Mr. Kirk, Third Security, LLC and NRM VII Holdings I, LLC have sole voting and dispositive power with respect to 3,333,333 shares of Common Stock and warrants to purchase 2,500,000 shares of Common Stock exercisable within 60 days of the date of this prospectus held by NRM VII Holdings I, LLC, and (b) Mr. Kirk and Intrexon Corporation have shared voting and dispositive power with respect to 1,034,483 shares of Common Stock held by Intrexon Corporation. The address of the principal business office of Mr. Kirk is 2875 South Ocean Boulevard, Suite 214, Palm Beach, Florida 33480. The address of the principal business office of NRM VII Holdings I, LLC is c/o Third Security, LLC, 1881 Grove Avenue, Redford, Virginia 24141. The address of the principal business office of Intrexon Corporation is 20358 Seneca Meadows Parkway, Germantown, Maryland 20876.



Table of Contents

- (2) On May 16, 2013, Paolo Cavazza, on his own behalf and on behalf of Sigma-Tau Finanziaria S.p.A., Sigma-Tau International S.A., Sigma-Tau America S.A. and Sigma-Tau Pharmaceuticals, Inc., filed Amendment No. 4 to Schedule 13D with the SEC, which amends the Schedule 13D filed with the SEC on February 20, 2009 as amended by Amendment No. 1 filed with the SEC on October 2, 2009, Amendment No. 2 filed with the SEC on June 28, 2010 and Amendment No. 3 filed with the SEC on January 2, 2013 (the "Schedule 13D"). The Schedule 13D indicates that (a) Mr. Cavazza has sole voting and dispositive power with respect to (i) 59,539 shares held by Mr. Paolo Cavazza and (ii) 164,146 shares of common stock and warrants to purchase 87,854 shares held by SINAF SA, and (b) Mr. Cavazza, Sigma-Tau Finanziaria S.p.A., Sigma-Tau International S.A., Sigma-Tau America S.A. and Sigma-Tau Pharmaceuticals, Inc. have shared voting and dispositive power with respect to 2,711,392 shares of common stock and warrants to purchase 357,069 shares of common stock exercisable within 60 days of the date of this prospectus held by Sigma-Tau Pharmaceuticals, Inc. Sigma-Tau Pharmaceuticals, Inc. is a direct wholly-owned subsidiary of Sigma-Tau America S.A., which is a direct wholly-owned subsidiary of Sigma-Tau International S.A., which is a direct wholly-owned subsidiary of Sigma-Tau Finanziaria S.p.A. Mr. Paolo Cavazza directly and indirectly owns 38% of Sigma-Tau Finanziaria S.p.A. SINAF SA is an indirect wholly owned subsidiary of Aptafin S.p.A., which is owned by Mr. Paolo Cavazza and members of his family. Mr. Paolo Cavazza's address is Via Tesserte, 10, Lugano, Switzerland. The business address of Sigma-Tau Finanziaria S.p.A. is Via Sudafrica, 20, Rome, Italy 00144. The business address of Sigma-Tau International S.A. is 19-21 Boulevard du Prince Henri, L-1724 Luxembourg. The business address of Sigma-Tau America S.A. is 19-21 Boulevard du Prince Henri, L-1724 Luxembourg. The business address of Sigma-Tau Pharmaceuticals, Inc. is 9841 Washingtonian Boulevard, Suite 500, Gaithersburg, Maryland 20878.
- (3) Includes 59,681 shares of common stock owned by Dr. Schaber, options to purchase 621,875 shares of common stock exercisable within 60 days of the date of this prospectus, and warrants to purchase 9,119 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (4) Includes options to purchase 173,444 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Brey is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (5) Includes 48,781 shares of common stock, options to purchase 64,156 shares of common stock exercisable within 60 days of the date of this prospectus, and warrants to purchase 29,268 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (6) Includes 48,809 shares of Common Stock, options to purchase 21,638 shares of common stock exercisable within 60 days of the date of this prospectus and warrants to purchase 17,857 shares of Common Stock exercisable within 60 days of the date of this prospectus. The address of Mr. Zeldis is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (7) Includes options to purchase 25,000 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Straube is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (8) Includes 12,195 shares of common stock, options to purchase 63,725 shares of common stock exercisable within 60 days of the date of this prospectus, and warrants to purchase 7,317 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (9)

Includes 19,047 shares of Common Stock, options to purchase 46,638 shares of common stock exercisable within 60 days of the date of this prospectus and warrants to purchase 14,286 shares of Common Stock exercisable within 60 days of the date of this prospectus. The address of Mr. Brownlie is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(10) Includes options to purchase 106,878 shares of common stock owned by Mr. Warusz exercisable within 60 days of the date of this prospectus. The address of Mr. Warusz is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(11) Includes options to purchase 15,000 shares of common stock owned by Dr. Brughera exercisable within 60 days of the date of this prospectus. The address of Dr. Brughera is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

\* Indicates less than 1%.

Table of Contents

TRANSACTIONS WITH RELATED  
PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS

Related Party Transactions

Other than the employment agreements, compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2013.

Director Independence

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

Table of Contents

THE LINCOLN PARK TRANSACTION

General

On November 18, 2013, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park purchased 285,714 shares of our common stock for \$600,000 and has agreed to purchase from us up to \$10,600,000 in the aggregate of our common stock (subject to certain limitations) from time to time over a 36-month period. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Concurrently with the execution of the Purchase Agreement on November 18, 2013, we issued to Lincoln Park 97,656 shares of our common stock as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement and 285,714 shares of our common stock in consideration of \$600,000 in an Initial Purchase. Other than the shares of our common stock that we have already issued to Lincoln Park as described above, we do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter and upon satisfaction of the other conditions set forth in the Purchase Agreement, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 75,000 shares on any single business day so long as at least one business day has passed since the most recent purchase. We can also increase the amount of our common stock to be purchased under certain circumstances to up to 100,000 shares but not exceeding \$750,000 per purchase plus an additional “accelerated amount” under certain circumstances. The purchase price per share is based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount. We issued 97,656 shares of our stock to Lincoln Park as a commitment fee for entering into the Purchase Agreement and we are obligated to issue up to an additional 122,070 shares pro rata as Lincoln Park purchases up to \$10,000,000 of our common stock as directed by us. For example, if we elect, at our sole discretion, to require Lincoln Park to purchase \$100,000 of our stock then we would issue 1,221 shares of the pro rata commitment fee which is the product of \$100,000 (the amount we have elected to sell) divided by \$10,000,000 (the amount we can sell Lincoln Park under the Purchase Agreement multiplied by 122,070 (the total number of pro rata commitment shares). The pro rata commitment shares will only be issued pursuant to this formula as and when we elect at our discretion to sell stock to Lincoln Park. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Purchase of Shares Under the Purchase Agreement

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 75,000 shares of our common stock on any such business day so long as one business day has passed since the last purchase. On any day that the closing sale price of our common stock is not below \$2.50 the purchase amount may be increased, at our sole discretion, to up to 100,000 shares of our common stock per purchase provided that the amount cannot exceed \$750,000 (a “Regular Purchase”). The purchase price per share for each such Regular Purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date of such shares.





## Table of Contents

In addition to Regular Purchases described above, we may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice and the closing price of our common stock is not below \$1.50 per share, to purchase an additional amount of our common stock (an "Accelerated Purchase"), not to exceed the lesser of:

- 30% of the aggregate shares of our common stock traded during normal trading hours on the purchase date; and
- two times the number of purchase shares purchased pursuant to the corresponding Regular Purchase.

The purchase price per share for each such Accelerated Purchase will be equal to the lower of:

- 95% of the volume weighted average price during (i) the entire trading day on the purchase date, if the volume of shares of our common stock traded on the purchase date has not exceeded a volume maximum calculated in accordance with the Purchase Agreement, or (ii) the portion of the trading day of the purchase date (calculated starting at the beginning of normal trading hours) until such time at which the volume of shares of our common stock traded has exceeded such volume maximum; or

· the closing sale price of our common stock on the purchase date.

In the case of both Regular Purchases and Accelerated Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as set forth above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

### Minimum Purchase Price

Under the Purchase Agreement, we have set a floor price of \$1.00 per share. Lincoln Park shall not purchase any shares of our common stock on any day that the closing sale price of our common stock is below the floor price. The floor price will be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction and, effective upon the consummation of any such event, the floor price will be the lower of (i) the adjusted price and (ii) \$1.00.

### Events of Default

Events of default under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;
- suspension by our principal market of our common stock from trading for a period of three consecutive business days;
- the de-listing of our common stock from our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NASDAQ Global Market, the NASDAQ Global Select Market, the NASDAQ Capital Market, the NYSE Amex or the OTC Bulletin Board (or nationally recognized

successor thereto);

- the transfer agent's failure for five business days to issue to Lincoln Park shares of our common stock which Lincoln Park is entitled to receive under the Purchase Agreement;
- any breach of the representations or warranties or covenants contained in the Purchase Agreement or any related agreement which has or which could have a material adverse effect on us subject to a cure period of five business days;
- any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or
- if at any time we are not eligible to transfer our common stock electronically or a material adverse change in our business, financial condition, operations or prospects has occurred.

## Table of Contents

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside of Lincoln Park's control, shares of our common stock cannot be sold by us or purchased by Lincoln Park under the Purchase Agreement.

### Our Termination Rights

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

### No Short-Selling or Hedging by Lincoln Park

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

### Effect of Performance of the Purchase Agreement on Our Stockholders

All shares of common stock registered in this offering are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 36 months commencing on the date that the registration statement including this prospectus becomes effective. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Lincoln Park may ultimately purchase all, some or none of the shares of common stock not yet issued but registered in this offering. If we sell these shares to Lincoln Park, Lincoln Park may sell all, some or none of such shares. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to \$10,600,000 of our common stock. Depending on the price per share at which we sell our common stock to Lincoln Park, we may be authorized to issue and sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus. If we choose to do so, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

Table of Contents

The following table sets forth the amount of additional gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement at varying purchase prices:

Assumed Average Purchase Price Per Share	Number of Registered Shares to be Issued if Full Purchase (1)(2)	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (3)	Proceeds from the Sale of Shares to Lincoln Park Under the \$10M Purchase Agreement
\$1.00 (4)	3,441,504	14.92%	\$3,400,000
\$1.50	3,462,256	15.00%	\$5,100,000
\$1.90 (5)	3,478,857	15.06%	\$6,460,000
\$2.50	3,503,760	15.15%	\$8,500,000
\$3.00	3,455,403	14.97%	\$10,000,000

- (1) Although the Purchase Agreement provides that we may sell up to an additional \$10,000,000 of our common stock to Lincoln Park, we are only registering 3,905,440 shares under this prospectus, which may or may not cover all the shares we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. As a result, we have included in this column only those shares that we are registering in this offering including the applicable additional commitment shares issuable to Lincoln Park.
- (2) The number of registered shares to be issued excludes the 97,656 previously issued commitment shares registered hereunder because no proceeds will be attributable to such commitment shares.
- (3) The denominator is based on 19,626,439 shares outstanding as of January 7, 2014, which includes the 97,656 shares issued to Lincoln Park as commitment shares in connection with this offering and 285,714 shares already purchased for proceeds of \$600,000, and is adjusted to include the number of shares set forth in the adjacent column which we would have sold to Lincoln Park at the applicable assumed average purchase price per share. The numerator does not include the 97,656 shares issued to Lincoln Park as commitment shares in connection with this offering, and is based on the number of shares registered in this offering to be issued under the Purchase Agreement as purchased by Lincoln Park at the applicable assumed purchase price per share set forth in the adjacent column. The number of shares in such column does not include shares that may be issued to Lincoln Park under the Purchase Agreement which are not registered in this offering.
- (4) Under the Purchase Agreement, we may not sell and Lincoln Park may not purchase any shares on a day in which the closing sale price of our common stock is below \$1.00, as may be adjusted in accordance with the Purchase Agreement.
- (5) The closing sale price of our shares on January 7, 2014.

#### SELLING STOCKHOLDER

This prospectus relates to the possible resale by the selling stockholder, Lincoln Park, of shares of common stock that have been or may be issued to Lincoln Park pursuant to the Purchase Agreement. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on November 18, 2013 concurrently with our execution of the Purchase Agreement, in which we agreed to provide certain registration rights with respect to sales by Lincoln Park of the shares of our common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

Lincoln Park, as the selling stockholder, may, from time to time, offer and sell pursuant to this prospectus any or all of the shares that we have sold or may sell to Lincoln Park under the Purchase Agreement. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

Table of Contents

The following table presents information regarding the selling stockholder and the shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the selling stockholder, and reflects its holdings as of January 7, 2014. Neither Lincoln Park nor any of its affiliates has held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. As used in this prospectus, the term “selling stockholder” includes Lincoln Park and any donees, pledgees, transferees or other successors in interest selling shares received after the date of this prospectus from Lincoln Park as a gift, pledge or other non-sale related transfer. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. The percentage of shares beneficially owned prior to the offering is based on 19,626,439 shares of our common stock actually outstanding as of December 12, 2013.

Selling Stockholder	Percentage of Outstanding Shares		Number Of Shares Beneficially Owned After this Offering	Percentage of Outstanding Shares	
	Beneficially Owned Before this Offering	Beneficially Owned Before this Offering		Beneficially Owned After this Offering	Beneficially Owned After this Offering
Lincoln Park Capital Fund, LLC (1)	383,370(2)	1.95%(3)	3,905,440(4)	--	*

\* Less than 1%

- (1) Josh Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park. Messrs. Scheinfeld and Cope have shared voting and investment power over the shares being offered under this prospectus.
- (2) Represents 97,656 shares of our common stock issued to Lincoln Park on November 18, 2013 as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement and 285,714 shares of our common stock issued to Lincoln Park in connection with the \$600,000 Initial Purchase, all of which shares are covered by the registration statement that includes this prospectus. See the description under the heading “The Lincoln Park Transaction” for more information about the Purchase Agreement.
- (3) Based on 19,626,439 outstanding shares of our common stock as of January 7, 2014, which includes 97,656 shares of our common stock issued to Lincoln Park on November 18, 2013 as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement and 285,714 shares of our common stock issued to Lincoln Park in connection with the \$600,000 Initial Purchase. Although we may at our discretion elect to issue to Lincoln Park up to an aggregate amount of \$10,600,000 of our common stock under the Purchase Agreement, other than the shares described in the immediately preceding sentence, such shares are not included in determining the percentage of shares beneficially owned before this offering.
- (4) Assumes issuance of the maximum 3,905,440 shares being registered hereby, which reflects the 383,370 shares already issued and the issuance of an additional 3,400,000 shares under the Purchase Agreement and 122,070 additional commitment shares.

Table of Contents

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholder, Lincoln Park. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus could be effected in one or more of the following methods:

ordinary brokers' transactions;

transactions involving cross or block trades;

through brokers, dealers, or underwriters who may act solely as agents;

“at the market” into an existing market for the common stock;

in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;

in privately negotiated transactions; or

any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

Lincoln Park is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act.

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions. In compliance with the guidelines of the Financial Industry Regulatory Authority, Inc. (“FINRA”), the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions. Neither we nor Lincoln Park can presently estimate the amount of compensation that any agent will receive.

We know of no existing arrangements between Lincoln Park or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters or dealers and any compensation from the selling stockholder, and any other required information.

We will pay the expenses incident to the registration, offering, and sale of the shares to Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.



## Table of Contents

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

Our common stock is quoted on the OTCQB under the symbol "SNGX".

### DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 50,350,000 shares of capital stock, of which 50,000,000 shares are common stock, par value \$0.001 per share, 230,000 shares are preferred stock, 10,000 shares are Series B Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding), 10,000 shares are Series C Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding) and 100,000 shares are Series A Junior Participating Preferred Stock, par value \$0.001 per share (which are available for issuance under our shareholder rights plan). As of the date of this prospectus, there were issued and outstanding 19,626,439 shares of common stock, options to purchase 2,151,511 shares of common stock and warrants to purchase 8,156,526 shares of common stock.

#### Common Stock

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

#### Preferred Stock

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

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

#### Series B Preferred Stock

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

## Table of Contents

### Voting

Each holder of Series B Preferred Stock is entitled to the number of votes equal to the number of whole shares of common stock into which the shares of Series Preferred Stock held by such holder is then convertible (as adjusted from time to time pursuant to the Certificate of Incorporation) with respect to any and all matters presented to the stockholders for their action or consideration. Except as provided by law, holders of Series B Preferred Stock vote together with the holders of common stock as a single class.

### Dividends

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

### Conversion

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

### Liquidation

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

### Redemption

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

### Junior Preferred Stock

#### Voting

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

#### Dividends

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

## Table of Contents

### Liquidation

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

### Shareholder Rights Plan

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

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

### Anti-Takeover Provisions

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

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

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

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

shareholders from bringing matters before an annual meeting of shareholders or from making nominations for directors at an annual meeting of shareholders.

Table of Contents

## Warrants

As of the date of this prospectus, warrants for the issuance of 8,156,526 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of \$2.17 per share.

## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

## Market information

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

Period	Price Range	
	High	Low
Year Ended December 31, 2012:		
First Quarter	\$ 1.01	\$ 0.44
Second Quarter	\$ 0.53	\$ 0.23
Third Quarter	\$ 0.55	\$ 0.26
Fourth Quarter	\$ 0.77	\$ 0.38
Year Ending December 31, 2013:		
First Quarter	\$ 2.13	0.55
Second Quarter	\$ 1.97	\$ 0.96
Third Quarter	\$ 2.39	\$ 1.00
Fourth Quarter	\$ 2.36	\$ 1.65

As of January 7, 2014, the last reported price of our common stock quoted on the OTCQB was \$1.90 per share. The OTCQB prices set forth above represent inter-dealer quotations, without adjustment for retail mark-up, mark-down or commission, and may not represent the prices of actual transactions.

## Transfer Agent

Shares of our common stock are issued in registered form. American Stock Transfer & Trust Company, LLC, 6201 15th Avenue, Brooklyn, NY 11219 (Telephone: (718) 921-8200; Facsimile: (718) 765-8719) is the registrar and transfer agent for shares of our common stock.

## Holders of Common Stock

As of January 7, 2014, there were 679 holders of record of our common stock. As of such date, 19,626,439 shares of our common stock were issued and outstanding.

## Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005. In September 2007, our stockholders approved an amendment to the 2005 Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under the plan by 500,000 shares, bringing the total shares reserved for issuance under the plan to 1,000,000 shares. In September 2010, our stockholders approved a second amendment to the 2005 Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under the plan by 750,000 shares, bringing the total

shares reserved for issuance under the plan to 1,750,000 shares. In September 2013, our stockholders approved a third amendment to the 2005 Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under the plan by 1,250,000 shares, bringing the total shares reserved for issuance under the plan to 3,000,000 shares.



Table of Contents

The following table provides information, as of December 31, 2013 with respect to options outstanding under our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders (1)	2,051,511	\$ 2.63	775,924
Equity compensation plans not approved by security holders	-	-	-
<b>Total</b>	<b>2,051,511</b>	<b>\$ 2.63</b>	<b>775,924</b>

1 Includes our 1995 Amended and Restated Omnibus Incentive Plan and our 2005 Equity Incentive Plan. Our 1995 Plan expired in 2005 and thus no securities remain available for future issuance under that plan.

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

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

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

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

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

unenforceable.

62

---

Table of Contents

EXPERTS

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

LEGAL MATTERS

The validity of the shares of our common stock offered hereby will be passed upon by the law firm of Duane Morris LLP, Miami, Florida.

AVAILABLE INFORMATION

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

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

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

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

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

Table of Contents

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

Table of Contents

	Page
Consolidated Balance Sheets as of September 30, 2013 (unaudited) and December 31, 2012	F-2
Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2013 and 2012 (unaudited)	F-3
Consolidated Statements of Changes in Shareholders' Equity for the Nine Months Ended September 30, 2013 (unaudited)	F-4
Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2013 and 2012 (unaudited)	F-5
Notes to Consolidated Financial Statements	F-6
Consolidated Balance Sheets as of December 31, 2012 and 2011	F-17
Consolidated Statements of Operations for the Years Ended December 31, 2012 and 2011	F-18
Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2012 and 2011	F-19
Consolidated Statements of Cash Flows for the Years Ended December 31, 2012 and 2011	F-20
Notes to Consolidated Financial Statements	F-21
Report of Independent Registered Public Accounting Firm	F-35

---

Table of ContentsSoligenix, Inc. and Subsidiaries  
Consolidated Balance Sheets

	September 30, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$6,582,556	\$3,356,380
Grants receivable	161,835	339,308
Prepaid expenses	198,060	140,693
Total current assets	6,942,451	3,836,381
Office furniture and equipment, net	18,830	12,995
Intangible assets, net	688,766	855,728
Total assets	\$7,650,047	\$4,705,104
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$1,214,585	\$1,124,503
Warrant liability	9,975,899	-
Accrued compensation	55,554	29,495
Total current liabilities	11,246,038	1,153,998
Shareholders' equity (deficiency):		
Preferred stock; 350,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 50,000,000 shares authorized; 19,152,630 shares and 11,168,905 shares issued and outstanding in 2013 and 2012, respectively	19,152	11,169
Additional paid-in capital	129,717,665	125,820,318
Accumulated deficit	(133,332,808)	(122,280,381)
Total shareholders' equity (deficiency)	(3,595,991 )	3,551,106
Total liabilities and shareholders' equity (deficiency)	\$7,650,047	\$4,705,104

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

Table of Contents

Soligenix, Inc. and Subsidiaries  
Consolidated Statements of Operations  
For the Three and Nine Months Ended September 30, 2013 and 2012  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues, principally from grants	\$312,491	\$931,627	\$1,845,123	\$2,341,896
Cost of revenues	(245,864 )	(761,628 )	(1,517,469 )	(1,934,529 )
Gross profit	66,627	169,999	327,654	407,367
Operating expenses:				
Research and development	1,216,559	371,338	4,113,686	1,749,112
General and administrative	710,730	558,877	1,918,411	1,841,138
Total operating expenses	1,927,289	930,215	6,032,097	3,590,250
Loss from operations	(1,860,662 )	(760,216 )	(5,704,443 )	(3,182,883 )
Other income (expense):				
Change in fair value of warrant liability	(4,699,846 )	-	(5,349,422 )	-
Interest income, net	652	1,250	1,438	5,284
Net loss	\$(6,559,856 )	\$(758,966 )	\$(11,052,427 )	\$(3,177,599 )
Basic and diluted net loss per share	\$(0.34 )	\$(0.07 )	\$(0.78 )	\$(0.29 )
Basic and diluted weighted average common shares outstanding	19,040,339	11,138,373	14,160,157	11,127,374

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

Table of Contents

Soligenix, Inc. and Subsidiaries  
Consolidated Statements of Changes in Shareholders' Equity (Deficiency)  
For the Nine Months Ended September 30, 2013  
(Unaudited)

	Common Stock Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Total
Balance, December 31, 2012	11,168,905	\$ 11,169	\$ 125,820,318	\$ (122,280,381)	\$ 3,551,106
Common stock issued in Unit offering, net of offering cost of \$895,933	6,773,995	6,774	6,209,988	-	6,216,762
Warrants issued in Unit offering	-	-	(4,827,788 )	-	(4,827,788 )
Issuance of common stock to collaboration partner	1,034,483	1,034	1,498,966	-	1,500,000
Issuance of common stock to vendors	43,104	43	59,545	-	59,588
Issuance of shares from exercise of stock options and warrants	132,143	132	385,465	-	385,597
Stock-based compensation expense	-	-	571,171	-	571,171
Net loss	-	-	-	(11,052,427 )	(11,052,427)
Balance, September 30, 2013	19,152,630	\$ 19,152	\$ 129,717,665	\$ (133,332,808)	\$ (3,595,991 )

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

Table of Contents

Soligenix, Inc. and Subsidiaries  
 Consolidated Statements of Cash Flows  
 For the Nine Months Ended September 30,  
 (Unaudited)

	2013	2012
Operating activities:		
Net loss	\$(11,052,427)	\$(3,177,599)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	171,666	172,785
Common stock and warrants issued in exchange for services	1,559,588	15,000
Change in fair value of warrant liability	5,349,422	-
Restricted stock issued to employee	-	10,000
Stock-based compensation	571,171	382,774
Change in operating assets and liabilities:		
Grants receivable	177,473	123,900
Other receivable	-	574,157
Prepaid expenses	(57,367 )	(13,759 )
Accounts payable	90,082	(279,833 )
Accrued compensation	26,059	(100,940 )
Total adjustments	7,888,094	884,084
Net cash used in operating activities	(3,164,333 )	(2,293,515)
Investing activities:		
Purchase of office equipment	(10,539 )	(4,755 )
Net cash used in investing activities	(10,539 )	(4,755 )
Financing activities:		
Proceeds from sale of common stock, net	6,216,762	-
Proceeds from exercise of warrants and options	184,286	-
Net cash provided by financing activities	6,401,048	-
Net increase (decrease) in cash and cash equivalents	3,226,176	(2,298,270)
Cash and cash equivalents at beginning of period	3,356,380	5,996,668
Cash and cash equivalents at end of period	\$6,582,556	\$3,698,398
Supplemental disclosure of non cash investing and financing activities:		
Warrants issued in Unit Offering	\$ 4,827,788	\$-
Reclassification of warrant liability to additional paid in capital relating to warrants exercised	\$ 201,311	\$-

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



Table of Contents

Soligenix, Inc.  
Notes to Consolidated Financial Statements  
(Unaudited)

Note 1. Nature of Business

Basis of Presentation

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

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

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with FDA regulations, litigation, and product liability. Results for the quarter and nine months ended September 30, 2013 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of September 30, 2013, the Company had cash and cash equivalents of \$6,582,556 as compared to \$3,356,380 as of December 31, 2012, representing an increase of \$3,226,176 or 96%. As of September 30, 2013, the Company had working capital of \$5,672,312, which excludes the non-cash warrant liability of \$9,975,899, as compared to working capital of \$2,682,383 as of December 31, 2012, representing an increase of \$2,989,929, or 111%. The increase in cash and working capital was primarily the result of the receipt of net proceeds of \$6,216,762 received from our registered public offering offset by cash used in operating activities during the nine month period. For the nine months ended September 30, 2013, the Company’s cash used in operating activities was \$3,164,333 as compared to \$2,293,515 for the same period in 2012, representing an increase of \$870,818, or 38%. This increase is primarily related to the Company’s activities in preparation for initiating clinical trials in SGX942 for the treatment of oral mucositis, and SGX203 for the treatment of pediatric Crohn’s disease.

Management’s business strategy can be outlined as follows:

- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Initiate a Phase 2/3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn’s disease;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis and treatment of chronic graft –versus host disease (“GI GVHD”);

F-6

---

## Table of Contents

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;  
Advance the preclinical and manufacturing development of OrbeShield™ as a biodefense medical countermeasure for the treatment of GI ARS;  
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, an example of which is the recently announced collaboration with Intrexon Corporation.

Based on the Company's current rate of cash outflows, cash on hand, proceeds from grant programs and proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the first quarter of 2015.

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

The Company has approximately \$34.6 million in active government contract and grant funding still available to support its associated research programs through 2018. The Company plans to submit additional grant applications for further support of its programs with various funding agencies.

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

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

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

## Note 2. Summary of Significant Accounting Policies

### Principles of Consolidation

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

### Operating Segments

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

## Table of Contents

### Grants Receivable

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

### Intangible Assets

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

The Company did not incur any capitalizable patent related costs during the nine months ended September 30, 2013 and 2012.

### Impairment of Long-Lived Assets

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

The Company did not record any impairment of long-lived assets for the nine months ended September 30, 2013 or 2012.

### Fair Value of Financial Instruments

FASB ASC 820 — Fair Value Measurements and Disclosures, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us on September 30, 2013. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources,

while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

F-8

---

## Table of Contents

The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair value based on the short-term maturity of these instruments. The Company recognizes all derivative financial instruments as assets or liabilities in the financial statements and measures them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with the offering were accounted for as derivatives. See Note 4, Warrant Liabilities.

### Revenue Recognition

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

### Research and Development Costs

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

### Stock-Based Compensation

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

F-9

---

## Table of Contents

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

The Company granted 501,600 and 100,000 options during the nine months ended September 30, 2013 and 2012, respectively.

The fair value of options granted are estimated using the Black-Scholes option pricing model utilizing the following assumptions and are amortized ratably over the option vesting periods, which approximates the service period:

- a dividend yield of 0%;
- an expected life of 4 years;
- volatility of 165% - 167% and 160% for 2013 and 2012, respectively;
- forfeitures at rate of 12%; and
- risk-free interest rates of 0.96% - 1.17% and 0.51% in 2013 and 2012, respectively.

## Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through September 30, 2013 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2013 and 2012. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at September 30, 2013 or 2012. Tax years beginning in 2010 for federal purposes are generally subject to examination by the taxing authorities, although net operating losses from those years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

## Earnings Per Share

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



Table of Contents

	2013		Three Months Ended September 30,		2012	
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	\$(6,559,856)	19,040,339	\$(0.34 )	\$(758,966 )	11,138,373	\$(0.07 )

	2013		Nine Months Ended September 30,		2012	
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	\$(11,052,427)	14,160,157	\$(0.78 )	\$(3,177,599)	11,127,374	\$(0.29 )

Shares issuable upon the exercise of options and warrants outstanding at September 30, 2013 and 2012 were 1,915,324 and 1,475,224 shares issuable upon the exercise of outstanding stock options, and 8,152,776 and 2,707,819 shares issuable upon the exercise of outstanding warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at September 30, 2013 were \$2.58 and \$2.17 per share, respectively. No options or warrants were included in the 2013 and 2012 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

## Use of Estimates and Assumptions

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

## Note 3. Intangible Assets

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

	Weighted Average Remaining Amortization Period (years)	Cost	Accumulated Amortization	Net Book Value
September 30, 2013				
Licenses	7.0	\$462,234	\$ 272,391	\$ 189,843
Patents	2.8	1,893,185	1,394,262	498,923
Total	3.6	\$2,355,419	\$ 1,666,653	\$688,766
December 31, 2012				
Licenses	7.7	\$462,234	\$ 252,019	\$210,215
Patents	3.3	1,893,185	1,247,672	645,513
Total	4.2	\$2,355,419	\$ 1,499,691	\$855,728

Amortization expense was \$56,266 and \$62,384 for the three months ended September 30, 2013 and 2012, respectively, and \$166,962 and \$167,573 for the nine months ended September 30, 2013 and 2012, respectively.

F-11

---

Table of Contents

Based on the balance of licenses and patents at September 30, 2013, the expected annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
2013	\$ 222,800
2014	\$ 213,200
2015	\$ 61,800
2016	\$ 61,800
2017	\$ 20,800

## Note 4. Warrant Liabilities

Warrants issued in connection with the Company's registered public offering contain provisions that protect holders from a decline in the issue price of its common stock (or "down-round" provisions) and contain net settlement provisions. The Company accounts for these warrants as liabilities instead of equity. Down-round provisions reduce the exercise or conversion price of a warrant if a company issues equity shares for a price that is lower than the exercise or conversion price of the warrants. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of exercising the warrant by paying cash. The Company evaluates whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a "fixed-for-fixed" option.

The Company recognizes these warrants as liabilities at their fair value on the date of grant and remeasures them at fair value on each reporting date.

The Company recognized an initial warrant liability for the warrants issued in connection with the registered public offering completed in June 2013. The initial warrant liability recognized on the related warrants totaled \$4,827,788, which was based on the June 25, 2013 closing price of a share of our common stock as reported on OTC Markets of \$0.96. On September 30, 2013, the closing price of our common stock as reported on OTC Markets was \$2.09. Due to the fluctuations in the market value of our common stock from June 25, 2013 through September 30, 2013, we recognized a non-cash charge of \$5,349,422 for the change in the fair value of the warrant liability during the nine months ended September 30, 2013.

The assumptions used in connection with the valuation of warrants issued were as follows:

	September 30, 2013	Initial Measurement June 25, 2013		
Number of shares underlying the warrants	5,309,438	5,416,851		
Exercise price	\$ 1.65	\$ 1.65		
Volatility	142 %	140 %		
Risk-free interest rate	1.39 %	1.49 %		
Expected dividend yield	0	0		
Expected warrant life (years)	4.74	5		
Stock Price	\$ 2.09	\$ 0.96		

F-12

---

Table of Contents

## Recurring Level 3 Activity and Reconciliation

The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3). The table reflects losses for the nine months ended September 30, 2013 for the financial liability categorized as Level 3 as of September 30, 2013.

## Fair Value Measurements Using Significant Unobservable Inputs (Level 3):

	Initial Measurement June 25, 2013	Decrease from Warrants Exercised in 2013	Increase in Fair Value	September 30, 2013
Warrant liability	\$ 4,827,788	\$ (201,311 )	\$ 5,349,422	\$ 9,975,899

## Note 5. Income Taxes

The Company had NOLs at December 31, 2012 of approximately \$79,454,000 for federal tax purposes and approximately \$9,478,000 of New Jersey NOL carry forwards remaining after the sale of unused NOL carry forwards, portions of which are currently expiring each year until 2031. In addition, the Company had \$2,860,000 of various tax credits that started expiring in December 2012 and will continue to expire through December 2030. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code (“IRC”) Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is possible that the utilization of the NOLs, could be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to Federal income tax assessment for years before 2010 for federal and 2009 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

The Company has no tax provision for the three and nine month periods ended September 30, 2013 and 2012 due to losses incurred and full valuation allowances recorded against net deferred tax assets.

## Note 6. Shareholders’ Equity

## Preferred Stock

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

## Common Stock

During the nine months ended September 30, 2013, the Company issued the following shares of common stock:

On June 25, 2013, the Company completed a public unit offering consisting of one share of common stock and an additional warrant of 0.75 share of common stock. The Company issued 6,773,995 shares of common stock which included 5,416,851 five-year warrants with an exercise price of \$1.65;  
1,034,483 shares of common stock issued to Intrexon Corporation in connection with an exclusive channel collaboration;  
107,143 shares of common stock issued upon the exercise of warrants;  
43,104 shares of common stock issued to vendors as partial consideration for services performed;  
25,000 shares of common stock issued upon the exercise of vested stock options.

Table of Contents

## Note 7. Commitments and Contingencies

The Company has commitments of approximately \$356,300 as of September 30, 2013 for several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

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

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

As a result of the above agreements, the Company has future contractual obligations as of September 30, 2013 over the next five years as follows:

Year	Research and Development	Property and Other Leases	Total
2013	\$ 31,300	\$ 26,400	\$ 57,700
2014	100,000	101,200	201,200
2015	75,000	24,900	99,900
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	\$ 356,300	\$ 152,500	\$ 508,800

Table of Contents

## Note 8. Operating Segments

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

	Three Months Ended September 30,	
	2013	2012
Revenues, Principally from Grants		
Vaccines/BioDefense	\$264,920	\$862,919
BioTherapeutics	47,571	68,708
Total	\$312,491	\$931,627
Loss from Operations		
Vaccines/BioDefense	\$(419,929 )	\$19,190
BioTherapeutics	(1,080,436)	(155,713 )
Corporate	(360,297 )	(623,693 )
Total	\$(1,860,662)	\$(760,216 )
Amortization and Depreciation Expense		
Vaccines/BioDefense	\$28,316	\$31,357
BioTherapeutics	29,233	32,180
Corporate	551	495
Total	\$58,100	\$64,032
Other Income /(Expense), Net		
Corporate	\$(4,699,194)	\$1,250
Stock-Based Compensation		
Vaccines/BioDefense	\$39,493	\$29,103
BioTherapeutics	158,142	(49,275 )
Corporate	209,256	167,944
Total	\$406,891	\$147,772



Table of Contents

	Nine Months Ended September 30,	
	2013	2012
<b>Revenues, Principally from Grants</b>		
Vaccines/BioDefense	\$1,683,265	\$2,170,761
BioTherapeutics	161,858	171,135
Total	\$1,845,123	\$2,341,896
<b>Income (Loss) from Operations</b>		
Vaccines/BioDefense	\$(1,983,396)	\$(111,319 )
BioTherapeutics	(2,068,703)	(1,363,572)
Corporate	(1,652,344)	(1,707,992)
Total	\$(5,704,443)	\$(3,182,883)
<b>Amortization and Depreciation Expense</b>		
Vaccines/BioDefense	\$83,951	\$84,308
BioTherapeutics	86,303	86,913
Corporate	1,412	1,564
Total	\$171,666	\$172,785
<b>Other Income /(Expense), Net</b>		
Corporate	\$(5,347,984)	\$5,284
<b>Stock-Based Compensation</b>		
Vaccines/BioDefense	\$61,742	\$33,363
BioTherapeutics	205,083	63,339
Corporate	304,346	286,072
Total	\$571,171	\$382,774
	As of	As of
	September	December
	30,	31,
	2013	2012
<b>Identifiable Assets</b>		
Vaccines/BioDefense	\$442,407	\$628,494
BioTherapeutics	411,847	566,111
Corporate	6,795,793	3,510,499
Total	\$7,650,047	\$4,705,104

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

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

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

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

Table of Contents

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

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

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

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

Table of Contents

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

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

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

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

Table of Contents

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

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

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

Table of Contents

Soligenix, Inc. and Subsidiaries  
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

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

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

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

Liquidity

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

Management’s business plan can be outlined as follows:

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

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

F-21

---

## Table of Contents

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

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

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

Explore other business development and merger/acquisition strategies.

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

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

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

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

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

## Reverse Stock Split

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

## Note 2. Summary of Significant Accounting Policies

### Principles of Consolidation

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

### Operating Segments



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

F-22

---

## Table of Contents

### Grants Receivable

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

### Intangible Assets

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

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

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

### Impairment of Long-Lived Assets

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

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

### Fair Value of Financial Instruments

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



## Table of Contents

### Revenue Recognition

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

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

### Research and Development Costs

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

### Stock-Based Compensation

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

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

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

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

a dividend yield of 0%;

an expected life of 4 years;

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

F-24

---

Table of Contents

forfeitures at a rate of 12%; and

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

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

## Income Taxes

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

## Earnings Per Share

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

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

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



Table of Contents

## Use of Estimates and Assumptions

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

## Note 3. Intangible Assets

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

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

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

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

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

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

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



Table of Contents

## Note 4. Income Taxes

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

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

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

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

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

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

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

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

program in future.

F-27

---

Table of Contents

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

Note 5. Shareholders' Equity

Preferred Stock

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

Common Stock

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

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

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

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

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

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

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

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

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

## Table of Contents

### Warrants

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

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

### Equity Line

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

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

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

The Fusion equity line expired in October 2011.

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

#### Stock Option Plans

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

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

Table of Contents

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

## Warrants to Purchase Common stock

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

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

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

F-31

---



Table of Contents

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

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

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

## Note 7. Concentrations

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

## Note 8. Commitments and Contingencies

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

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

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

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



Table of Contents

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

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

Table of Contents

## Note 9. Operating Segments

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

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

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

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders,

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

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

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

/s/ EisnerAmper LLP

Jenkintown, PA  
February 25, 2013

F-35

---

Table of Contents

---

---

SOLIGENIX, INC.

3,905,440 SHARES OF COMMON STOCK

---

PROSPECTUS

---

January 16, 2014

---

---