SOLIGENIX, INC.
Form S-1
August 03, 2015

As filed with the Securities and Exchange Commission on August 3, 2015.

Registration No. 333-_____

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

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

Soligenix, Inc.

29 Emmons Drive, Suite C-10

Princeton, New Jersey 08540

(609) 538-8200

(Address, including zip code, and telephone number, including area code,

of registrant's principal executive offices)

Christopher J. Schaber, Ph.D.

President and Chief Executive Officer

Soligenix, Inc.

29 Emmons Drive, Suite C-10

Princeton, New Jersey 08540

(609) 538-8200

(Name, address, including zip code, and telephone number,

including area code, of agent for service)

with copies to:

Leslie J. Croland, Esq.

Duane Morris LLP

200 South Biscayne Boulevard

Suite 3400

Miami, Florida 33131-2318

(305) 960-2200

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Amount to be registered (1) (2)**	**Proposed maximum offering price per share (2) (3)**	**Proposed maximum aggregate offering price (2) (3)**	**Amount of registration fee (2) (3)**
Common Stock, $0.001 par value per share (4)	8,661,603	$ 1.725	$14,941,265.18	$ 1,737

(1) The shares of our common stock being registered hereunder are being registered for sale by the selling stockholders, as defined in the accompanying prospectus.

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issuable to prevent dilution resulting from stock splits, stock dividends, or similar transactions.

(3) Estimated solely for purposes of calculating the registration fee according to Rule 457(c) under the Securities Act of 1933, as amended, on the basis of the average of the bid and asked prices of the Registrant's common stock reported on the OTCQB on July 28, 2015.

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

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

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

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED AUGUST 3, 2015

SOLIGENIX, INC.

8,661,603 SHARES OF COMMON STOCK

This prospectus relates to the offer and sale, from time to time, of up to 8,661,603 shares of the common stock of Soligenix, Inc., a Delaware corporation ("Soligenix," "we," "us," and "our,"), by the selling stockholders named in this prospectus in the section "Selling Stockholders," whom we refer to in this document as the "selling stockholders." Of the shares of common stock being offered by the selling stockholders, 7,627,120 may be issued pursuant to the equity purchase agreements that we entered into with Kodiak Capital Group, LLC ("Kodiak Capital"), Kingsbrook Opportunities Master Fund LP ("Kingsbrook") and River North Equity, LLC ("River North"), which we refer to in this prospectus as the "Purchase Agreements." Please refer to the section of this prospectus entitled "The Equity Purchase Transactions" for a description of the Purchase Agreements and the section entitled "Selling Stockholders" for additional information regarding the selling stockholders. Kodiak Capital, Kingsbrook and River North are sometimes referred to herein collectively as the "Equity Purchasers" and individually as the "Equity Purchaser."

We are not selling any shares of common stock in this offering. We, therefore, will not receive any proceeds from the sale of the shares by the selling stockholders. We will, however, receive proceeds from the sale of securities pursuant to our exercise of the put right under the Purchase Agreements.

The Equity Purchasers are "underwriters" within the meaning of the Section 2(a)(11) of the Securities Act of 1933, as amended. The other selling stockholder may be deemed to be "underwriters" within the meaning of the Securities Act of 1933, as amended.

The selling stockholders may sell common stock from time to time in the principal market on which the stock will be traded at the prevailing market price or in negotiated transactions. See "Plan of Distribution" for more information about how the selling stockholders may sell the shares of common stock being registered pursuant to this prospectus. The selling stockholders have informed us that they do not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

We have paid and 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 July 28, 2015, the last quoted sale price of our common stock as reported on the OTCQB was $1.72 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 _____, 2015

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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 securities 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.

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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 "Where You Can Find More Information."

Business Overview

We are a late-stage biopharmaceutical company developing product candidates intended to address unmet medical needs in areas of inflammation, oncology, and biodefense. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a first-in-class photo-dynamic therapy (SGX301) utilizing safe, visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"), 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) and acute radiation enteritis (SGX201), and our novel innate defense regulator technology (SGX942) for the treatment of oral mucositis in head and neck cancer.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, VeloThrax™, our anthrax vaccine candidate, OrbeShield™, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs is supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government contract funding. With the recently awarded government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We plan to use the funds received under our government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and NIAID to advance the development of OrbeShield™ for the treatment of GI ARS. Additionally, we have entered into a global and exclusive channel collaboration with Intrexon Corporation ("Intrexon") through which we intend to develop and commercialize a human monoclonal antibody therapy (SGX101) to treat melioidosis.

An outline for our business strategy follows:

Conduct a Phase 3 clinical trial for SGX301 for the treatment of CTCL;

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

Initiate a Phase 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;

Develop RiVax™ and VeloThrax™ in combination with our ThermoVax™ technology, 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 merger/acquisition strategies, an example of which is our collaboration with Intrexon.

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Product Candidates in Development

The following tables summarize our product candidates under development:

BioTherapeutic Product Candidates

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
SGX301	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate ($p \leq 0.04$) compared to placebo; Phase 3 clinical trial planned for the second half of 2015, with data expected in the second half of 2016
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial initiated in the second half of 2013, with data expected in the second half of 2015
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed June 2013, efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed; Phase 3 clinical trial planned for the second half of 2015, with data expected in the second half of 2017
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated; Phase 2 trial planned for the first half of 2016, with data expected in the first half of 2017

Vaccine Thermostability Platform**

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

BioDefense Product Candidates**

Soligenix Product Candidate	Indication	Stage of Development

RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete, safety and neutralizing antibodies for protection demonstrated; Phase 1/2 trial planned for the second half of 2015
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2016
OrbeShield™	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943/SGX101	Melioidosis	Pre-clinical program initiated

**Contingent upon continued government contract and grant funding.

Corporate Information

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987, we merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to "Immunotherapeutics, Inc." We changed our name to "Endorex Corp." in 1996, to "Endorex Corporation" in 1998, to "DOR BioPharma, Inc." in 2001, and finally to "Soligenix, Inc." in 2009. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

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The Offering

This prospectus relates to the offer and sale from time to time of up to 8,661,603 shares of our common stock by the selling stockholders, 1,034,483 shares of which were issued to Intrexon Corporation in a private placement on April 27, 2013 as consideration for the execution and delivery of a collaboration agreement.

Kodiak Capital, Kingsbrook and River North, three of the selling stockholders under this prospectus, are offering for sale up to 3,389,831 shares, 3,389,831 shares and 847,458 shares, respectively, of our common stock. None of Kodiak Capital, Kingsbrook or River North is an affiliate of, or has any relation to, any of the other selling stockholders named herein. On July 29, 2015, we entered into the Purchase Agreements with Kodiak Capital, Kingsbrook and River North. Pursuant to the Purchase Agreements, Kodiak Capital, Kingsbrook and River North have agreed to purchase from us up to an aggregate of $5 million, $4 million and $1 million, respectively, worth of shares of our common stock from time to time, until December 31, 2016. Also on July 29, 2015, we entered into Registration Rights Agreements (the "Registration Rights Agreements") with the Equity Purchasers, 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 may be issued to the Equity Purchasers under the Purchase Agreements. In consideration for entering into the Purchase Agreements, we issued to each of the Equity Purchasers a promissory note having a principal amount equal to 3% of the amount committed by it, which are payable April 15, 2016.

We do not have the right to commence any sales to the Equity Purchasers under the Purchase Agreements 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 the Equity Purchasers to purchase shares of our common stock, but we would be unable to sell shares to them if such purchase would result in their respective beneficial ownership equaling more than 9.99% of the outstanding common stock. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreements, and we will control the timing and amount of any sales of our common stock to the Equity Purchasers. The purchase price of the shares that may be sold to the Equity Purchasers under the Purchase Agreements will be equal to 80% of the lowest daily volume weighted average price of the common stock for the five consecutive trading days immediately following our request for the Equity Purchasers to purchase the shares. We may at any time in our sole discretion terminate the Purchase Agreements without fee, penalty or cost upon one business day notice. None of the Equity Purchasers may assign or transfer its rights and obligations under the Purchase Agreements.

As of July 28, 2015, there were 26,381,976 shares of our common stock outstanding, of which 18,798,079 shares were held by non-affiliates. Although the Purchase Agreements provide that we may sell up to $5 million, $4 million and $1 million worth of shares of our common stock to Kodiak Capital, Kingsbrook and River North, respectively, only 7,627,120 shares of our common stock are being offered under this prospectus. If all of the 7,627,120 shares offered by the Equity Purchasers under this prospectus were issued and outstanding as of the date hereof, such shares would represent 22.43% of the total number of shares of our common stock outstanding and 28.87% 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

7,627,120 shares offered under this prospectus to the Equity Purchasers, 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 the Equity Purchasers is dependent upon the number of shares we sell to them under the Purchase Agreements.

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 the Equity Purchasers.

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Securities Offered

Common stock offered by the selling stockholders:	8,661,603 shares, including 7,627,120 that we may sell to the Equity Purchasers under the Purchase Agreements.
Common stock outstanding prior to the offering:	26,381,976 shares.
Common stock to be outstanding after giving effect to the total issuance of 7,627,120 shares to the Equity Purchasers under the Purchase Agreements registered hereunder:	34,009,096 shares.
	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 7,627,120 shares to the Equity Purchasers under the Purchase Agreements registered hereunder, excludes the following:
Shares issuable upon exercise of outstanding options and warrants:	329,397 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 2,338,237 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of $2.31 per share; and
	4,941,119 shares of common stock issuable upon exercise of outstanding warrants as of the date of this prospectus with a weighted average exercise price of $0.82 per share.
Use of proceeds:	We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders in this offering. However, we may receive up to $10 million from sales of shares to the Equity Purchasers under the Purchase Agreements. Any proceeds that we receive from sales to the Equity Purchasers under the Purchase Agreements will be used to further develop our late-stage 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

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RISK FACTORS

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

Risks Related to our Business

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

We have experienced significant losses since inception and, at March 31, 2015, had an accumulated deficit of approximately $143.6 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of March 31, 2015, we had approximately $5.0 million in cash available. Based on our projected budgetary needs, funding from existing contracts and grants over the next two years and sales to Lincoln Park Capital Fund, LLC ("Lincoln Park") under our $10.6 million equity facility and to the Equity Purchasers under the $10 million Purchase Agreements, we expect to be able to maintain the current level of our operations for at least the next twelve months.

We have sufficient funds through our existing biodefense grant facilities from the NIAID, a division of the National Institutes of Health (the "NIH"), and BARDA to finance our biodefense projects for the next six years. In September 2014, we entered into a contract with the NIH for the development of RiVax™ to protect against exposure to ricin toxin that would provide up to $24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH. 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. In July 2012, we received an additional Small Business Innovation and Research ("SBIR") grant from NIAID for $600,000 and in February 2014, we were awarded a one-year NIAID SBIR grant award of approximately $300,000 to further evaluate SGX943 as a treatment for melioidosis. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component associated with our existing contracts and grants will fund some fixed costs for direct employees working on these contracts and grants as well as other administrative costs.

Our product candidates are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of these product candidates. From inception through March 2015, we have expended approximately $61.9 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least $16.1 million over the next twelve months in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements of which approximately $10.4 million will be reimbursed through our existing government contracts and grants. 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.

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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 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, or may fail to obtain marketing approval.

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 be unable 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.

We expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a late-stage biopharmaceutical company. Our operations to date have been primarily limited to developing our technology and undertaking pre-clinical studies and clinical trials of our product candidates in our two active business segments, BioTherapeutics and Vaccines/BioDefense. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this prospectus and also include:

our ability to obtain additional funding to develop our product candidates;

delays in the commencement, enrollment and timing of clinical trials;

the success of our product candidates through all phases of clinical development;

any delays in regulatory review and approval of product candidates in clinical development;

our ability to obtain and maintain regulatory approval for our product candidates in the United States and foreign jurisdictions;

potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies, or cause an approved drug to be taken off the market;

our dependence on third-party contract manufacturing organizations (“CMOs”) to supply or manufacture our products;

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our dependence on contractors to conduct our clinical trials;

our ability to establish or maintain collaborations, licensing or other arrangements;

market acceptance of our product candidates;

our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;

competition from existing products or new products that may emerge;

the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;

our ability to discover and develop additional product candidates;

our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;

our ability to attract and retain key personnel to manage our business effectively;

our ability to build our finance infrastructure and improve our accounting systems and controls;

potential product liability claims;

potential liabilities associated with hazardous materials; and

our ability to obtain and maintain adequate insurance policies.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We have no approved products on the market and therefore do not expect to generate any revenues from product sales in the foreseeable future, if at all.

To date, we have no approved product on the market and have not generated any significant product revenues. We have funded our operations primarily from sales of our securities and from government grants. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential or successfully obtain government procurement or stockpiling agreements. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

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 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 U.S. Food and Drug Administration (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 is uncertain as to outcome, and requires 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. 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.

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.

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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 product recalls and suspension or withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by governmental authorities in the U.S. and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

There may be unforeseen challenges in developing our biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans, referred to as the Animal Rule. 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. Further, other countries have not, at this time, established criteria for review and approval of these types of products outside their normal review process, i.e., there is no Animal Rule equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the United States and internationally have the capability to test animals with anthrax or ricin, or otherwise assist us in qualifying the requisite animal models. We have to compete with other biodefense companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe or at all.

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

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

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If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products. We do not have or 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 may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we are currently focusing on the regulatory approval of certain product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on

existing and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in an area in which it would have been more advantageous to enter into a partnering arrangement.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved New Drug Application ("NDA") is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials.

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Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market.

Even if the FDA approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid. Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product; cost-effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payers; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The degree of market acceptance of any product that we develop will depend on a number of factors, including:

- cost-effectiveness;
- the safety and effectiveness of our products, including any significant potential side effects, as compared to alternative products or treatment methods;
- the timing of market entry as compared to competitive products;
- the rate of adoption of our products by doctors and nurses;
- product labeling or product insert required by the FDA for each of our products;
- reimbursement policies of government and third-party payors;

effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and

unfavorable publicity concerning our products or any similar products.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by major pharmaceutical companies, biotechnology companies and manufacturers of generic drugs. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept and utilize any of our product candidates. If our products do not achieve market acceptance, we will not be able to generate significant revenues or become profitable.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and could require us to seek additional financing.

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

We do not have extensive experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. To obtain the expertise necessary to successfully 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.

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

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

Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Serious adverse events or undesirable side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials may show that our product candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

If any of our product candidates cause serious adverse events or undesirable side effects:

- regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product;

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;

we may be required to limit the patients who can receive the product;

we may be subject to limitations on how we promote the product;

sales of the product may decrease significantly;

regulatory authorities may require us to take our approved product off the market;

we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

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 partnership with Intrexon.

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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 the 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 were separately billed at that time. 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.

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

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

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

We currently rely on license agreements from New York University, Yeda Research and Development Company Ltd., 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 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.

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

Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force 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 $10 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 use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.

Our research and development processes and/or those of our third party contractors may involve the controlled use of hazardous materials and chemicals. These hazardous chemicals are reagents and solvents typically found in a

chemistry laboratory. Our operations also may produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. While we attempt to comply with all environmental laws and regulations, including those relating to the outsourcing of the disposal of all hazardous chemicals and waste products, we cannot eliminate the risk of contamination from or discharge of hazardous materials and any resultant injury. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations.

Compliance with environmental laws and regulations may be expensive. Current or future environmental regulations may impair our research, development or production efforts. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks.

We may agree to indemnify our collaborators in some circumstances against damages and other liabilities arising out of development activities or products produced in connection with these collaborations.

In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

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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. 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.

Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non-patent exclusivity and/or the listing with the FDA by the competitor of patents covering its newly-approved drug product. Periods of non-patent exclusivity for new versions of existing drugs such as our current product candidates can extend up to three and one-half years. See “Business—The Drug Approval Process.”

These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and biotechnology companies that are pursuing other forms of treatment for the same indications we are pursuing and that have greater financial and other resources. Other companies may succeed in developing products earlier than us, obtaining FDA approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

There can be no assurance that any of our product candidates will be accepted by the marketplace as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA. Even if our products are successfully developed and approved for use by all governing regulatory bodies, there can be no assurance that physicians and patients will accept our product(s) as a treatment of choice.

Furthermore, the pharmaceutical research industry is diverse, complex, and rapidly changing. By its nature, the business risks associated therewith are numerous and significant. The effects of competition, intellectual property disputes, market acceptance, and FDA regulations preclude us from forecasting revenues or income with certainty or even confidence.

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 17 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.

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

During recent months, there has been substantial volatility 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.

Risks Related to our Intellectual Property

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 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 (the “PTO”) regarding the breadth of claims allowed in biotechnology patents.

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

It is also possible that our owned and 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 to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

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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.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Also, a third party may assert that our patents are invalid and/or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

Interference proceedings brought before the PTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have

priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our common stock could be adversely affected.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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Risks Related to our Common Stock

Our common stock price is highly volatile.

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

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

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

our quarterly operating results and performance;

developments or disputes concerning patents or other proprietary rights;

acquisitions;

litigation and government proceedings;

adverse legislation;

changes in government regulations;

our available working capital;

economic and other external factors; and

general market conditions.

Since January 1, 2014, the closing stock price of our common stock has fluctuated between a high of $2.50 per share to a low of $0.95 per share. On July 28, 2015, the last quoted sale price of our common stock as reported on the OTCQB was $1.72 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock by the Company, as well as 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, but provides significantly less liquidity than national market systems such as the NYSE MKT. 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.

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

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

As of March 31, 2015, we had a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximately 6,085,714 shares of our common stock at a current weighted average exercise price of approximately $1.25; and

- options to purchase approximately 2,272,022 shares of our common stock at a current weighted average exercise price of approximately $2.34.

We also have 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.

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

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Since our common stock is not listed on a national securities exchange, U.S. holders of warrants may not be able to exercise their warrants without compliance with applicable state securities laws and the value of your warrants may be significantly reduced.

Since our securities are not listed for trading on a national exchange, the exercise of the warrants by U.S. holders may not be exempt from state securities laws. As a result, depending on the state of residence of a holder of the warrants, a U.S. holder may not be able to exercise its warrants unless we comply with any state securities law requirements necessary to permit such exercise or an exemption applies. Although we plan to use our reasonable efforts to assure that U.S. holders will be able to exercise their warrants under applicable state securities laws if no exemption exists, there is no assurance that we will be able to do so. As a result, your ability to exercise your warrants may be limited. The value of the warrants may be significantly reduced if U.S. holders are not able to exercise their warrants under applicable state securities laws.

Our common stock is deemed to be a "penny stock," which may make it more difficult for investors to sell their shares due to suitability requirements.

Our common stock is subject to Rule 15g-1 through 15g-9 under the Securities Exchange Act of 1934, as amended, which imposes certain sales practice requirements on broker-dealers which sell our common stock to persons other than established customers and "accredited investors" (generally, individuals with a net worth in excess of $1,000,000 or annual incomes exceeding $200,000 (or $300,000 together with their spouses)). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. This rule adversely affects the ability of broker-dealers to sell our common stock and the ability of our stockholders to sell their shares of common stock.

Additionally, our common stock is subject to the SEC regulations for "penny stock." Penny stock includes any equity security that is not listed on a national exchange and has a market price of less than $5.00 per share, subject to certain exceptions. The regulations require that prior to any non-exempt buy/sell transaction in a penny stock, a disclosure schedule set forth by the SEC relating to the penny stock market must be delivered to the purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker-dealer and the registered representative and current price quotations for the common stock. The regulations also require that monthly statements be sent to holders of penny stock that disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements adversely affect the market liquidity of our common stock.

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 the Company, our stockholders may not recoup all or any portion of their investment.

In the event of a liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the proceeds and/or assets of the 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 the Company. In this event, our stockholders could lose some or all of their investment.

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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 a purchase agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $10.6 million 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 partial fee for its commitment to purchase shares of our common stock under the purchase agreement and 285,714 shares of common stock for an aggregate price of $600,000. From November 18, 2013 through July 28, 2015, we sold 825,000 additional shares to Lincoln Park and issued 19,354 additional shares to Lincoln Park as additional commitment shares under the purchase agreement and received proceeds of approximately $1.6 million. The shares that may be sold pursuant to the purchase agreement in the future may be sold by us to Lincoln Park at our discretion from time to time over the remaining term of approximately 16 months from the date of 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 additional 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.

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

On July 29, 2015, we entered into the Purchase Agreements with the Equity Purchasers. Pursuant the Purchase Agreements, the Equity Purchasers have committed to purchase up to an aggregate of $10 million of our common stock. The shares that may be sold pursuant to the Purchase Agreements in the future may be sold by us to the Equity Purchasers at our discretion from time to time, commencing after the SEC has declared effective the registration statement that includes this prospectus until December 31, 2016. The per share purchase price for the shares that we may sell to the Equity Purchasers under the Purchase Agreements will fluctuate based on the price of our common stock, and will be equal to 80% of the lowest daily volume weighted average price of the common stock for the five consecutive trading days immediately following our request for the Equity Purchasers to purchase the shares.

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 the Equity Purchasers, except that, pursuant to the terms of the Purchase Agreements, we would be unable to sell shares to the Equity Purchasers if such purchase would result in an Equity Purchaser's respective beneficial ownership equaling more than 9.99% of the outstanding common stock. The Equity Purchasers may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the Purchase Agreements and, after they have acquired shares, the Equity Purchasers may sell all, some or none of those shares. Therefore, sales to the Equity Purchasers 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 the Equity Purchasers, 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.

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The Equity Purchasers will pay less than the then-prevailing market price for our common stock.

The common stock to be issued to the Equity Purchasers pursuant to the Purchase Agreements will be purchased at an twenty percent (20%) discount to the lowest daily volume weighted average price of the common stock for the five consecutive trading days immediately following our request for the Equity Purchasers to purchase the shares. The Equity Purchasers have a financial incentive to sell our common stock immediately upon receiving the shares to realize the profit equal to the difference between the discounted price and the market price. If the Equity Purchasers sell the shares, the price of our common stock could decrease. If our stock price decreases, the Equity Purchasers may have a further incentive to sell the shares of our common stock that they hold. These sales may have a further impact on our stock price.

The issuance of our common stock pursuant to the terms of the asset purchase agreement with Hy Biopharma Inc. may cause dilution and the issuance of such shares of common stock, or the perception that such issuances may occur, could cause the price of our common stock to fall.

On April 1, 2014, we entered into an option agreement pursuant to which Hy Biopharma Inc. ("Hy Biopharma") granted us an option to purchase certain assets, properties and rights (the "Hypericin Assets") related to the development of Hy Biopharma's synthetic hypericin product candidate for the treatment of CTCL, which we refer to as SGX301, from Hy Biopharma. In exchange for the option, we paid $50,000 in cash and issued 43,067 shares of common stock in the aggregate to Hy Biopharma and its assignees. We subsequently exercised the option, and on September 3, 2014, we entered into an asset purchase agreement with Hy Biopharma, pursuant to which we purchased the Hypericin Assets. Pursuant to the purchase agreement, we paid $250,000 in cash and issued 1,849,113 shares of common stock in the aggregate to Hy Biopharma and its assignees, and may issue up to an aggregate of $10 million worth of our common stock (subject to a cap equal to 19.99% of our issued and outstanding common stock) in the aggregate upon attainment of specified milestones. Also on September 3, 2014, we entered into the Registration Rights Agreement with Hy Biopharma, pursuant to which we have filed a registration statement with the SEC.

The number of shares that we may issue under the purchase agreement will fluctuate based on the market price of our common stock. Depending on market liquidity at the time, the issuance of such shares may cause the trading price of our common stock to fall.

We may ultimately issue all, some or none of the additional shares of our common stock that may be issued pursuant to the purchase agreement. We are required to register any shares issued pursuant to the purchase agreement for resale under the Securities Act. After any such shares are registered, the holders will be able to sell all, some or none of those shares. Therefore, issuances by us under the purchase agreement could result in substantial dilution to the interests of other holders of our common stock. Additionally, the issuance of a substantial number of shares of our common stock pursuant to the purchase agreement, or the anticipation of such issuances, 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.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The information contained in this prospectus includes forward-looking statements. These forward-looking statements are often identified by words such as “may,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “continue,” “plan,” “poten 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;
- uncertainty as to whether our product candidates will be safe and effective to support regulatory approvals;
- significant uncertainty inherent in developing vaccines against bioterror threats, and manufacturing and conducting preclinical and clinical trials of vaccines;
- our ability to obtain future financing or funds when needed, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;
- that product development and commercialization efforts will be reduced or discontinued due to difficulties or delays in clinical trials or a lack of progress or positive results from research and development efforts;
- our ability to obtain further grants and awards from the U.S. Government and other countries, and maintenance of our existing grants;
- our ability to enter into any biodefense procurement contracts with the U.S. Government or other countries;

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

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

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

changes in healthcare regulation;

changes in the needs of biodefense procurement agencies;

maintenance and progression of our business strategy;

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

our expectations about the potential market sizes and market participation potential for our product candidates may not be realized;

our expected revenues (including sales, milestone payments and royalty revenues) from our product candidates and any related commercial agreements of ours may not be realized;

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.

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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.

Industry Data and Market Information

This prospectus contains estimates, projections and other statistical data made by independent parties and by us relating to market size and growth, the potential value of government procurement contracts, the incidence of certain medical conditions and other industry data. These data, to the extent they contain estimates or projections, involve a number of subjective assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Industry publications and other reports we have obtained from independent parties generally state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. While we believe that the data from these industry publications and other reports are generally reliable, we have not independently verified the accuracy or completeness of such data. These and other factors could cause results to differ materially from those expressed in these publications and reports.

We have provided estimates of the potential worldwide market or value of potential government procurement contracts for certain of our product candidates. These estimates are based on a number of factors, including our expectation as to the number of patients with a certain medical condition that would potentially benefit from a particular product candidate, the current costs of treating patients with the targeted medical condition, our expectation that we will be able to demonstrate to the FDA’s satisfaction in our clinical trials that the product candidate is safe and effective, our belief that our product candidate would, if approved, have an assumed treatment cost per patient, historic values of government procurement contracts for vaccines, and our expectation of the dosage of the product candidate. While we have determined these estimates based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. Among these factors are the following: there is no assurance that the product candidate will prove to be safe and effective or will ultimately be approved for sale by the FDA; any FDA approval of the product candidate may contain restrictions on its use or require warning labels; third party payors may not be willing to provide reimbursement for product candidate at the assumed price per patient; the government may not be willing to procure our vaccine candidates in amounts or at costs similar to its historic procurement activities; the dosage that ultimately may be approved may be different from the assumed dosage; and doctors may not adopt the product candidate for use as quickly or as broadly as we have

assumed. It is possible that the ultimate market for a product candidate or value of procurement contracts will differ significantly from our expectations due to these or other factors. As a result of these and other factors, investors should not place undue reliance on such estimates. See “Risk Factors:”

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholders. We will not receive any proceeds upon the sale of shares by the selling stockholders in this offering. However, we may receive gross proceeds of up to $10 million under the Purchase Agreements with the Equity Purchasers, assuming that we sell the full amount of our common stock that we have the right, but not the obligation, to sell to the Equity Purchasers under those agreements. See “Plan of Distribution” elsewhere in this prospectus for more information.

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We currently expect to use the net proceeds from the sale of shares to the Equity Purchasers under the Purchase Agreements to further develop our late-stage product candidates and for other general corporate purposes. We will have broad discretion in determining how we will allocate the proceeds from any sales to the Equity Purchasers.

Even if we sell $10 million worth of shares of our common stock to the Equity Purchasers pursuant to the Purchase Agreements, we will need to obtain additional financing in the future in order to fully fund all of our planned research and development activities. We may seek additional capital in the private and/or public equity markets, pursue government contracts and grants as well as business development activities to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are evaluating additional equity financing opportunities on an ongoing basis 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.

DIVIDEND POLICY

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.

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 for the periods indicated, the high and low sales prices per share of our common stock as reported by the OTCQB.

	Price Range	
Period	**High**	**Low**
Year Ended December 31, 2013:		
First Quarter	$2.13	$0.55
Second Quarter	$2.05	$0.86
Third Quarter	$2.48	$0.98

Fourth Quarter	$2.36	$1.65
Year Ended December 31, 2014:		
First Quarter	$2.50	$1.75
Second Quarter	$2.29	$1.65
Third Quarter	$2.25	$1.67
Fourth Quarter	$2.09	$0.91
Year Ending December 31, 2015:		
First Quarter	$2.30	$0.98
Second Quarter	$2.95	$1.36
Third Quarter (through July 28, 2015)	$2.48	$1.66

On July 28, 2015, the last reported price of our common stock quoted on the OTCQB was $1.72 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 July 28, 2015, there were 545 holders of record of our common stock. As of such date, 26,381,976 shares of our common stock were issued and outstanding.

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Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005. In September 2007, our stockholders approved an amendment to the 2005 Equity Incentive Plan to increase the maximum number of shares of our common stock available for issuance under the plan by 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. The following table provides information, as of December 31, 2014 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]	2,488,279	$ 2.40	184,045
Equity compensation plans not approved by security holders	-	-	-
Total	2,488,279	$ 2.40	184,045

[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.

In April 2015, our Board of Directors approved the 2015 Equity Incentive Plan, which was approved by stockholders on June 18, 2015. A maximum of 3,000,000 shares of our common stock are available for issuance under the 2015

Equity Incentive Plan. As of July 28, 2015, no grants have been made under the 2015 Equity Incentive Plan.

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 March 31, 2015, we had a negative net tangible book value of $(2,181,751), or approximately $(0.09) per share of common stock.

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Dilution in net tangible book value per share represents the difference between the assumed offering price per share of common stock of $1.72 (the closing price of our common stock on July 28, 2015) and the pro forma as adjusted net tangible book value per share of common stock immediately after the sale of $10 million to the Equity Purchasers under the Purchase Agreements. Therefore, after giving effect to our assumed receipt of $10 million in estimated net proceeds from the issuance of 7,267,441 shares of common stock under the Purchase Agreements (which is the maximum dollar amount that we may receive under the Purchase Agreements) and registered in this offering (assuming a purchase price of $1.376 per share, 80% of the closing price of the common stock on July 28, 2015, and assuming such sale was made on March 31, 2015, and after deducting estimated offering commissions and expenses payable by us), our pro forma as adjusted net tangible book value as of March 31, 2015 would have been approximately $7,359,749, or $0.23 per share. This would represent an immediate increase in the net tangible book value of $0.32 per share to existing shareholders attributable to this offering. The following table illustrates this per share dilution:

Assumed offering price per share of common stock		$1.72
Net tangible book value per share as of March 31, 2015	$(0.09)	
Increase in as adjusted net tangible book value per share attributable to the sale of shares under the Purchase Agreements	0.32	
Pro forma net tangible book value per share after the sale of shares under the Purchase Agreements		0.23
Dilution per share to new investors		$1.49

To the extent that we sell less than $10 million worth of shares under the Purchase Agreements, or to the extent that some or all sales are made at prices lower than or in excess of the assumed price per share of $1.376, then the dilution reflected in the table above will differ. The above table is based on 26,381,976 shares of our common stock outstanding as of March 31, 2015, adjusted for the assumed sale of $10 million in shares to the Equity Purchasers under the Purchase Agreements at the assumed purchase price described above and after deducting estimated offering commissions and expenses payable by us.

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.

The number of shares of our common stock reflected in the discussion and calculations for the figures appearing in the table above is based on 25,339,364 shares of our common stock outstanding as of March 31, 2015 and excludes, as of that date:

2,272,022 shares issuable upon exercise of outstanding options with a weighted average exercise price of $2.34;

6,085,714 shares issuable upon exercise of outstanding warrants with a weighted average exercise price of $1.25; and

400,302 shares available for future issuance under our equity incentive plans.

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 "Cautionary Note Regarding Forward-Looking Statements."

Our Business Overview

We were incorporated in Delaware in 1987. We are a late-stage biopharmaceutical company developing product candidates intended to address unmet medical needs in the areas of inflammation, oncology and biodefense. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

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Our BioTherapeutics business segment is developing a first-in-class photo-dynamic therapy (SGX301) utilizing safe, visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"), 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) and acute radiation enteritis (SGX201), and our novel innate defense regulator technology (SGX942) for the treatment of oral mucositis in head and neck cancer.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, VeloThrax™, our anthrax vaccine candidate, OrbeShield™, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs is supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government contract funding. With the recently awarded government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We plan to use the funds received under our government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and NIAID to advance the development of OrbeShield™ for the treatment of GI ARS. Additionally, we have entered into a global and exclusive channel collaboration with Intrexon Corporation ("Intrexon") through which we intend to develop and commercialize a human monoclonal antibody therapy (SGX101) to treat melioidosis.

An outline of our business strategy follows:

- Conduct a Phase 3 clinical trial of SGX301 for the treatment of CTCL;
- Conduct a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Conduct a Phase 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 gastrointestinal ("GI") tract such as prevention of acute radiation enteritis;
- Develop RiVax™ and VeloThrax™ in combination with our ThermoVax™ technology 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 merger/acquisition strategies, an example of which is our collaboration with Intrexon.

Critical Accounting Policies

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

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Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, *Research and Development*. Based on this consideration, we capitalized payments made to legal firms that are engaged in filing and protecting rights to intellectual property rights for our current product candidates 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 industry partners. These rights can also be sold or sub-licensed as part of our strategy to partner our product candidates at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents designed to protect, preserve, maintain and perhaps extending the lives of the patents. We capitalize such costs and amortize intangibles over their expected useful life – generally a period of 11 to 16 years.

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

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 December 31, 2014. 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).

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. We recognize all derivative financial instruments as assets or liabilities in the financial statements and measure 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 our June 2013 offering were accounted for as derivatives.

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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 government contracts and grants. Recording of revenue is applied in accordance with FASB ASC 605, *Revenue Recognition* and/or ASC 605-25, *Revenue Recognition – Multiple Element Arrangements*. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant.

Accounting for Warrants

We considered FASB ASC 815, *Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock*, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock, and therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. We evaluated the provisions in our outstanding warrants and determined that warrants issued in connection with our June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of our common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants are recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. All other warrants issued were indexed to our own stock and therefore are accounted for as equity instruments for 2015 and 2014.

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% 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.

From time to time, we issue restricted shares of our 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.

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

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Results of Operations

Three Months Ended March 31, 2015 Compared to March 31, 2014

For the three months ended March 31, 2015, we had a net loss of $4,569,322 as compared to a net loss of $3,331,708 for same period in the prior year, representing an increase in the net loss of $1,237,614, or 37%. Included in the net loss for March 31, 2015 is a non-cash charge of $3,011,616 as compared to $1,742,090 for the same period in the prior year representing the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering.

For the three months ended March 31, 2015, revenues relate to government contracts and grants awarded in support of our development in OrbeShield™ in GI ARS and RiVax™. We had revenues of $816,286 as compared to $910,597 for the same period in the prior year, representing a decrease of $94,311, or 10%. The decrease in revenues was a result of our ThermoVax™ grant expiring during the fourth quarter of 2014.

We incurred costs related to those revenues for the three months ended March 31, 2015 and 2014 of $527,399 and $628,981, respectively, representing a decrease of $101,582, or 16%. These costs relate to allocated employee costs and payments due to subcontractors in connection with research performed pursuant to the contracts and grants.

Our gross profit for the three months ended March 31, 2015 was $288,887, as compared to $281,616 for the same period in 2014, representing an increase of $7,271, or 3%.

Research and development spending was $1,029,884 for the three months ended March 31, 2015 as compared to $1,030,621 for the same period in 2014, representing a nominal decrease.

General and administrative expenses were $817,270 for the three months ended March 31, 2015, as compared to $840,904 for the same period in 2014, representing a nominal decrease.

Other income (expense) for the three months ended March 31, 2015 was $(3,011,055) as compared to $(1,741,799) for the same period in 2014, representing an increase of $1,269,256, or 73%. The increase in expense is primarily attributable to a greater non-cash charge in 2015 compared to 2014 for the change in the fair value of the warrant

liability related to warrants issued in connection with our June 2013 registered public offering.

Year Ended December 31, 2014 Compared to 2013

For the year ended December 31, 2014, we had a net loss of $6,706,972 as compared to a net loss of $10,058,996 for the prior year, representing a decreased loss of $3,352,024 or 33%. Included in the net loss for December 31, 2014 is a non-cash gain of $3,436,195 versus a non-cash expense of $3,654,770 for December 31, 2013 which represents the change in the fair value of the warrant liability related to warrants issued in connection with our registered public offering in June 2013. During the third quarter of 2014, we completed the acquisition of Hypericin, SGX301, for which we issued common stock with a value of $3,750,000 and paid cash of $250,000 which was recognized as acquired in-process research and development expense. Additionally, we continued our progress on the Phase 2 clinical trial with SGX942 for patients suffering from oral mucositis associated with their chemoradiation therapy, (“CRT”) for head and neck cancer.

For the year ended December 31, 2014 and 2013, revenues and associated costs relate to government contracts and grants awarded in support of the development of ThermoVax™, RiVax™ GI-ARS, oBand OrbeShield™ in GI ARS. For the year ended December 31, 2014, we had revenues of $7,043,016 as compared to $3,224,152 for the prior year, representing an increase of $3,818,864 or 118%. The increase in revenues was a result of research and development activities performed under our government contracts associated with OrbeShield™ and the initiation of a research and development government contract in the fourth quarter for RiVax™.

We incurred costs related to contract and grant revenues in the year ended December 31, 2014 and 2013 of $5,313,855 and $2,544,285, respectively, representing an increase of $2,769,570 or 109%. These costs primarily relate to payments made to subcontractors and allocated employee costs in connection with research performed pursuant to contracts and grants. The fluctuations are due to the development activity performed on the contracts and grants discussed above.

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Our gross profit for the year ended December 31, 2014 was $1,729,161 as compared to $679,867 for the prior year, representing an increase of $1,049,294 or 154%. This increase is due primarily to the OrbeShield™ and RiVax™ contracts which provide a management fee and higher negotiated reimbursement for fixed overhead.

Research and development, including acquired in-process research and development costs, increased by $4,015,356 or 79%, to $9,086,535 for the year ended December 31, 2014 as compared to $5,071,179 for the prior year. This increase is primarily related to the acquisition of Hypericin, SGX301, for which we issued common stock with a value of $3,750,000 and paid cash of $250,000 which was recognized as acquired in-process research and development expense. Additionally, we continued our progress on the Phase 2 clinical trial with SGX942 for patients suffering from oral mucositis associated with their CRT for head and neck cancer.

General and administrative expenses increased by $638,745 or 23%, to $3,403,975 for the year ended December 31, 2014, as compared to $2,765,230 for the prior year. This increase is primarily related to increased headcount and an increase in outside professional services.

Other income (expense) for the year ended December 31, 2014 was $3,437,505 as compared to $(3,652,810) for the prior year. The change is primarily related to non-cash income of $3,436,195 which represents the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering for the year ended December 31, 2014 as compared to a non-cash expense of $(3,654,770) for the year ended December 31, 2013.

During the year ended December 31, 2014, 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 $616,872 of income tax benefit, net of transaction costs as compared to $750,356 for the year ended December 31, 2013. There can be no assurance as to the continuation or magnitude of this program in future years.

Business Segments

We maintained two active business segments for the year ended December 31, 2014 and December 31, 2013: Vaccines/BioDefense and BioTherapeutics.

Revenues for the Vaccines/BioDefense business segment for the year ended December 31, 2014 were $6,756,388 as compared to $3,003,822 for the year ended December 31, 2013, representing an increase of $3,752,566 or 125%. The increase in revenues were a result of our OrbeShield™ contracts and initiating the RiVax™ contract during the fourth quarter of 2014. Revenues for the BioTherapeutics business segment for the year ended December 31, 2014 were $286,628 as compared to $220,330 for the year ended December 31, 2013, representing an increase of $66,298 or 30%. This increase is primarily related to work performed under our GI ARS and oral mucositis grants.

Income (loss) from operations for the Vaccines/BioDefense business segment for the year ended December 31, 2014 was $807,164 as compared to $(1,666,130) for the year ended December 31, 2013. Income from operations is primarily attributable to our gross margins related to our government contracts. Loss from operations for the BioTherapeutics business segment for the year ended December 31, 2014 was $7,674,381 as compared to $3,069,998 for the year ended December 31, 2013, representing an increase of $4,604,383. This increased loss is due primarily to the acquisition of Hypericin, SGX301, for which we issued common stock with a value of $3,750,000 and paid cash of $250,000 which was recognized as acquired in-process research and development expense and our continued progress in the Phase 2 clinical trial with SGX942 for patients suffering from oral mucositis associated with their CRT for head and neck cancer.

Amortization and depreciation expense for the Vaccines/BioDefense business segment for the year ended December 31, 2014 was $39,625 as compared to $37,981 for the year ended December 31, 2013. Amortization and depreciation expense for the BioTherapeutics business segment for the year ended December 31, 2014 was $199,196 as compared to $190,033 for the year ended December 31, 2013.

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Financial Condition and Liquidity

Cash and Working Capital

As of March 31, 2015, we had cash and cash equivalents of $5,012,605 as compared to $5,525,094 as of December 31, 2014, representing a decrease of $512,489 or 9%. As of March 31, 2015, we had working capital of $2,913,440 as compared to working capital of $3,174,214 as of December 31, 2014, which excludes a non-cash warrant liability of $5,152,367 and $3,789,562, respectively, representing a decrease of $260,777, or 8%. This decrease is primarily related to expenditures to support the Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer.

Based on the Company's current rate of cash outflows, cash on hand, proceeds from government contract and grant programs, proceeds available from the Lincoln Park equity line 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 for at least the next twelve months, as of March 31, 2015.

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

We have up to $50.5 million in active contract and grant funding still available to support our associated research programs in 2015 and beyond. We plan to submit additional contract and grant applications for further support of these programs with various funding agencies.

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

We will pursue NOL sales in the State of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $616,872 in proceeds from the sale of NJ NOL in 2014, we expect to participate in the program during 2015 and beyond as the program is available.

We have a $10.6 million equity facility, with Lincoln Park, through October 2016, of which approximately $9.3 million is available as of March 31, 2015.

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

Expenditures

Under our budget and based upon our existing product development agreements, 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 $16.1 million before any grant reimbursements, of which $5.7 million relates to the BioTherapeutics business and $10.4 million relates to the Vaccines/BioDefense business. We anticipate contract and grant revenues in the next 12 months of approximately $10.4 million to offset research and development expenses in the Vaccines/BioDefense business segment.

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The table below details our costs for research and development by program and amounts reimbursed for the years ended December 31, 2014 and 2013, and the three months ended March 31, 2015 and 2014:

	Years Ended December 31,		**Three Months Ended March 31,**	
	2014	**2013**	**2015**	2014
Research & Development Expenses				
Oral BDP	$561,655	$1,467,077	$-	$271,438
RiVax™ & ThermoVax™ Vaccines	846,870	1,113,430	192,923	177,318
SGX94	2,820,807	659,809	513,442	495,294
SGX943/101	19,378	1,500,000	7,227	-
SGX301	4,369,585	-	247,396	-
Other	468,240	330,863	68,896	86,571
Total	$9,086,535	$5,071,179	$1,029,884	$1,030,621
Reimbursed under Government Contracts and Grants				
OrbeShield™	$4,100,663	$672,194	$294,313	$460,139
RiVax™ & ThermoVax™ Vaccines	930,573	1,872,091	165,814	168,842
Other	282,619	-	67,272	-
Total	$5,313,855	$2,544,285	$527,399	$628,981
Grand Total	$14,400,390	$7,615,464	$1,557,283	$1,659,602

Contractual Obligations

We have commitments of approximately $500,000 as of March 31, 2015 relating to several licensing agreements with consultants and universities. Additionally, we have collaboration and license agreements, which upon clinical or commercialization success may require the payment of milestones of up to $7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

In December 2014, we entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months is approximately $12,300 per month, or approximately $20.85 per square foot. This rent increases to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months, and thereafter to approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease.

On September 3, 2014, we entered into an asset purchase agreement with Hy Biopharma, Inc. (“Hy Biopharma”) pursuant to which we acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma’s synthetic hypericin product. As consideration for the assets acquired, we paid $250,000 in cash and issued 1,849,113 shares of common stock with a fair value of $3,750,000. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in our research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the United States. Provided all future success-oriented milestones are attained, we will be required to make payments of up to $10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company not to exceed 19.9% ownership of its outstanding stock.

On April 27, 2013, we entered into an exclusive channel collaboration agreement (the “Channel Agreement”) with Intrexon 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 targeting melioidosis. The Channel Agreement grants 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. The Channel Agreement, upon clinical or commercialization success, may require the payment of certain milestones payments up to $7 million, if and when achieved.

In February 2007, our Board of Directors authorized the issuance of 50,000 shares of our common stock to Dr. Schaber 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 us and/or our stockholders to a third party. Dr. Schaber’s amended employment agreement includes our obligation to issues such shares if such event occurs.

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

Year	Research and Development	Property and Other Leases	Total
April 1 through December 31, 2015	$ 100,000	$99,000	$199,000
2015	100,000	157,000	257,000
2016	100,000	152,000	252,000
2017	100,000	52,000	152,000
2018	100,000	-	100,000
Total	$ 500,000	$460,000	$960,000

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4) of Regulation S-K.

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BUSINESS

Our Business Overview

We are a late-stage biopharmaceutical company developing product candidates intended to address unmet medical needs in the areas of inflammation, oncology, and biodefense. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a first-in-class photo-dynamic therapy (SGX301) utilizing safe, visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"), 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) and acute radiation enteritis (SGX201), and our novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis in head and neck cancer.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, VeloThrax™, our anthrax vaccine candidate, OrbeShield™, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs is supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government contract funding. With the recently awarded government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We plan to use the funds received under our government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and NIAID to advance the development of OrbeShield™ for the treatment of GI ARS. Additionally, we have entered into a global and exclusive channel collaboration with Intrexon Corporation ("Intrexon") through which we intend to develop and commercialize a human monoclonal antibody therapy (SGX101) to treat melioidosis.

An outline for our business strategy follows:

Conduct a Phase 3 clinical trial for SGX301 for the treatment of CTCL;

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

Initiate a Phase 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;

Develop RiVax™ and VeloThrax™ in combination with our ThermoVax™ technology, 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 merger/acquisition strategies, an example of which is our collaboration with Intrexon.

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Corporate Information

We were incorporated in Delaware in 1987 under the name Biological Therapeutics, Inc. In 1987, we merged with Biological Therapeutics, Inc., a North Dakota corporation, pursuant to which we changed our name to "Immunotherapeutics, Inc." We changed our name to "Endorex Corp." in 1996, to "Endorex Corporation" in 1998, to "DOR BioPharma, Inc." in 2001, and finally to "Soligenix, Inc." in 2009. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Our Product Candidates in Development

The following tables summarize our product candidates under development:

BioTherapeutic Product Candidates

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
SGX301	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate ($p \leq 0.04$) compared to placebo; Phase 3 clinical trial planned for the second half of 2015, with data expected in the second half of 2016
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial initiated in the second half of 2013, with data expected in the second half of 2015
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed June 2013, efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed; Phase 3 clinical trial planned for the second half of 2015, with data expected in the second half of 2017
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated; Phase 2 trial planned for the first half of 2016, with data expected in the first half of 2017

Vaccine Thermostability Platform**

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

BioDefense Product Candidates**

Soligenix Product Candidate	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete, safety and neutralizing antibodies for protection demonstrated; Phase 1/2 trial planned for the second half of 2015
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2016
OrbeShield™	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943/SGX101	Melioidosis	Pre-clinical program initiated

** Contingent upon continued government contract and grant funding.

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BioTherapeutics Overview

SGX301 – for Treating Cutaneous T-Cell Lymphoma

SGX301 is a novel, first-in-class, photodynamic therapy that utilizes safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. Hypericin is also found in several species of *Hypericum* plants, although the drug used in SGX301 is chemically synthesized by a proprietary manufacturing process and not extracted from plants. Importantly, hypericin is optimally activated with visible light thereby avoiding the negative consequences of ultraviolet light. Other light therapies using UVA light result in serious adverse effects including secondary skin cancers.

Combined with photoactivation, in clinical trials hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from CTCL patients. In both settings, it appears that the mode of action is an induction of cell death in a concentration as well as a light dose-dependent fashion. These effects appear to result, in part, from the generation of singlet oxygen during photoactivation of hypericin.

Hypericin is one of the most efficient known generators of singlet oxygen, the key component for phototherapy. The generation of singlet oxygen induces necrosis and apoptosis in adjacent cells. The use of topical hypericin coupled with directed visible light results in generation of singlet oxygen only at the treated site. We believe that the use of visible light (as opposed to cancer-causing ultraviolet light) is a major advance in photodynamic therapy. In a published Phase 2 clinical study in CTCL, after six weeks of twice-weekly therapy, a majority of patients experienced a statistically significant (p-value ≤ 0.04) improvement with topical hypericin treatment whereas the placebo was ineffective: 58.3% compared to 8.3%, respectively.

SGX301 has received orphan drug designation as well as Fast Track designation from the United States Food and Drug Administration (the "FDA"). The Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven-year term of market exclusivity for SGX301 upon final FDA approval, orphan drug designation also positions us to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of FDA user fees for the potential submission of a New Drug Application ("NDA") for SGX301, and certain tax credits. In addition, 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 NDA for SGX301 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.

We anticipate initiating a Phase 3 clinical study of SGX301 in the treatment of CTCL in the second half of 2015.

We estimate the potential worldwide market for SGX301 is in excess of $250 million for all applications, including the treatment of CTCL. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements – Industry Data and Market Information.”

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Cutaneous T-Cell Lymphoma

CTCL is a class of non-Hodgkin's lymphoma ("NHL"), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs, which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These skin-trafficking malignant T-cells migrate to the skin, causing various lesions to appear that may change shape as the disease progresses, typically beginning as a rash and eventually forming plaques and tumors. Mycosis fungoides ("MF") is the most common form of CTCL. It generally presents with skin involvement only, manifested as scaly, erythematous patches. Advanced disease with diffuse lymph node and visceral organ involvement is usually associated with a poorer response rate to standard therapies. A relatively uncommon sub-group of CTCL patients present with extensive skin involvement and circulating malignant cerebriform T-cells, referred to as Sézary syndrome. These patients have substantially graver prognoses than those with MF.

CTCL mortality is related to stage of disease, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no FDA-approved drug for front-line treatment of early stage CTCL. Treatment of early-stage disease generally involves skin-directed therapies. One of the most common unapproved therapies used for early-stage disease is oral 5 or 8-methoxypsoralen ("Psoralen") given with ultraviolet A ("UVA") light, referred to as PUVA, which is approved for dermatological conditions such as disabling psoriasis not adequately responsive to other forms of therapy, idiopathic vitiligo and skin manifestations of CTCL in persons who have not been responsive to other forms of treatment. Psoralen is a mutagenic chemical that interferes with DNA causing mutations and other malignancies. Moreover, UVA is a carcinogenic light source that when combined with the Psoralen, results in serious adverse effects including secondary skin cancers; therefore, the FDA requires a Black Box warning for PUVA.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the approximate 500,000 individuals living with NHL. We estimate, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL, that it affects over 20,000 individuals in the U.S., with approximately 2,800 new cases seen annually.

SGX94

SGX94 is an IDR that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing.

SGX94 is based on a new class of short, synthetic peptides known as innate defense regulators ("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 represent 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 may be 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.

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 was shown to be safe and well-tolerated in all dose groups 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. We believe that market opportunities for SGX94 include mucositis, acute methicillin resistant *Staphylococcus aureus* (MRSA) bacterial infections, acinetobacter, melioidosis, acute radiation syndrome and as a vaccine adjuvant, with potential opportunities for non-dilutive funding to support the development.

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SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is our product candidate containing our IDR technology platform, SGX94, targeting the treatment of 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.

We initiated a Phase 2 clinical study of SGX942 in the treatment of oral mucositis in head and neck cancer patients in the second half of 2013.

We estimate the potential worldwide market for SGX942 is in excess of $500 million for all applications, including the treatment of oral mucositis. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements – Industry Data and Market Information."

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 GI 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 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 (greater than 80% incidence of severe mucositis) and is common 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 GI 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 are planning to pursue development programs in the treatment of pediatric Crohn’s disease, acute radiation enteritis 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 are pursuing orphan drug designations for relevant indications as appropriate in both the U.S. and Europe. An orphan drug designation provides seven and ten years of market exclusivity upon approval, in the U.S. and Europe, respectively.

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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 given SGX203 orphan drug designation as well as Fast Track designation for the treatment of pediatric Crohn's disease.

We anticipate initiating a Phase 3 clinical study of SGX203 in the treatment of pediatric Crohn's disease in the second half of 2015.

We estimate the potential worldwide market for oral BDP is in excess of $500 million for all applications, including the treatment of pediatric Crohn's disease. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements – Industry Data and Market Information."

Pediatric Crohn's Disease

Crohn's disease 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 approximately 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. In 2012, we completed a Phase 1/2 clinical trial testing SGX201 in prevention of acute radiation enteritis. Patients with rectal cancer scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. The objectives of the study were to evaluate the safety and maximal tolerated dose of escalating doses of SGX201, as well as the preliminary efficacy of SGX201 for prevention of signs and symptoms of acute radiation enteritis. The study demonstrated that oral administration of SGX201 was safe and well tolerated across all four dose groups. There was also evidence of a potential dose response with respect to diarrhea, nausea and vomiting and the assessment of enteritis according to National Cancer Institute Common Terminology Criteria for Adverse Events for selected gastrointestinal events. In addition, the incidence of diarrhea was lower than that seen in recent published historical control data in this patient population. This program was supported in part by a $500,000 two-year Small Business Innovation and Research (“SBIR”) grant awarded by the National Institutes of Health (“NIH”). We are currently working with our Radiation Enteritis medical advisory board in pursuing additional funding from the NIH to support the clinical development program.

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

We estimate the potential worldwide market for oral BDP is in excess of $500 million for all applications, including the treatment of acute radiation enteritis. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements – Industry Data and Market Information.”

Acute Radiation Enteritis

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

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

Symptoms will usually resolve within two to six 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.

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, we believe that 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 (“C”) and even brief excursions from this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. We believe that the savings realized from the elimination of cold chain costs and related product losses would significantly increase the profitability of vaccine products. We believe that elimination of the cold chain could 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.

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ThermoVax™ development was 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™ and our aluminum-adjuvanted anthrax vaccine, VeloThrax™. Each vaccine was manufactured, under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the key antigen. When RiVax™ was kept at 40 degrees C (104 degrees Fahrenheit) for up to one year, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. In contrast, animals that were vaccinated with the liquid RiVax™ vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C. When VeloThrax™ was kept for up to 16 weeks at 70 degrees C, it was able to develop a potent antibody response, unlike the liquid formulation kept at the same temperature. Moreover, we have also demonstrated the compatibility of our thermostabilization technology with other secondary adjuvants such as TLR-4 agonists.

Additionally, the University of Colorado conducted a study that demonstrated a heat stable vaccine formulation of a human papillomavirus (HPV) vaccine. The work was conducted by Drs. Randolph and Garcea and demonstrated the successful conversion of a commercial virus-like particle (VLP) based vaccine requiring cold-chain storage to a subunit, alum-adjuvanted, vaccine which is stable at ambient temperatures. This work, funded by a University of Colorado Seed grant and the Specialized Program of Research Excellence (SPORE) in cervical cancer, is the first demonstration of the utility of ThermoVax™ technology for the development of a subunit based commercial vaccine. The HPV vaccine formulation was found to be stable for at least 12 weeks at 50 degrees C. In the study, mice immunized with the ThermoVax™-stabilized HPV subunit vaccine were also found to achieve immune responses similar to the commercial HPV vaccine, Cervarix®, as measured by either total antibody levels or neutralizing antibody levels. Moreover, whereas the immune responses to Cervarix® were reduced after storage for 12 weeks at 50 degrees C, the ThermoVax™ formulated vaccine retained its efficacy. The results were published online in the European Journal of Pharmaceutics and Biopharmaceutics (see http://www.sciencedirect.com/science/article/pii/S0939641115002416).

We intend 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. We believe that ThermoVax™ also will enable us to expand our vaccine development expertise beyond biodefense into the infectious disease space and has the potential to allow for the development of multivalent vaccines (e.g., combination ricin-anthrax vaccine).

RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin, and if approved would be the first ricin vaccine. 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. RiVax™ has demonstrated statistically significant ($p < 0.0001$) preclinical survival results in a lethal aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, PNAS Epub ahead of print March 9, 2015), and has also been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies that we believe may 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 completed in September 2012, sponsored by University of Texas Southwestern Medical Center ("UTSW"), evaluated a more potent formulation of RiVax™ that contained an aluminum adjuvant (Alum). 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.

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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 UTSW where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. To date, we and UTSW have collectively received approximately $25 million in grant funding from the NIH for the development of RiVax™. In September 2014, we entered into a contract with the NIH for the development of RiVax™ that would provide up to an additional $24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH.

RiVax™ has 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. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements – Industry Data and Market Information."

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). In recent years, Al Qaeda in the Arabian Peninsula has 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 ricin vaccine, nor is there a known antidote for ricin toxin exposure.

VeloThrax™ – Anthrax Vaccine

VeloThrax™ is our proprietary vaccine candidate based on a recombinant protective antigen ("rPA") derivative intended for use against anthrax. We have 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 a protective antigen 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 protective antigen translocation step, anthrax toxin trafficking and function cease. We believe that VeloThrax™ is a more immunogenic candidate than native rPA. This apparent increase in immunogenicity suggests that the DNI rPA is processed and presented to the immune system more efficiently by cellular antigen processing pathways, which is consistent with known properties of the molecule.

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

We believe that 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. 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. We expect that VeloThrax™ will combine 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. We believe that VeloThrax™ has the potential to provide the Public Health Emergency Medical Countermeasures Enterprise ("PHEMCE") and the Department of Defense ("DoD") with a safe and stable alternative to the existing licensed anthrax vaccine product. We also intend 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. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements – Industry Data and Market Information."

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

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OrbeShield™ has demonstrated positive preclinical results in a canine GI ARS model which indicate that dogs treated with OrbeShield™ demonstrated statistically significant (p=0.04) improvement in survival with dosing at either 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. We are seeking to treat the same type of toxicity in our acute radiation enteritis clinical program with SGX201. As a result, we believe that OrbeShield™ has the potential to be a "dual use" compound, a desirable characteristic which is a specific priority of BARDA for ARS and other medical countermeasure indications. The FDA has cleared the IND application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS.

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. 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 given 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 contracts could reach as much as $450 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements – Industry Data and Market Information."

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

greater than 2 grays (“Gy”) of absorbed radiation 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. The GI tract is highly sensitive due to the continuous need for 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. As a result, we believe there is an urgent medical need for specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

SGX943/SGX101– for Treating Melioidosis

SGX943 uses the same active ingredient as SGX94 and is being developed in preclinical studies as a potential treatment for melioidosis. Because SGX943 directly targets the innate immune system (and does not attempt to kill the bacteria directly), we believe 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. In February 2014, we were awarded a one-year NIAID SBIR grant award of approximately $300,000 to further evaluate SGX943 as a potential treatment for melioidosis. Preclinical results to date have demonstrated that SGX943 treatment, in combination with standard of care antibiotics such as doxycycline, can statistically significantly enhance survival in a lethal murine pneumonic melioidosis model ($p< 0.001$).

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SGX101 is a human monoclonal antibody therapy being developed in preclinical studies as a potential treatment of melioidosis using Intrexon's advanced human antibody discovery, isolation, and production technologies. As data becomes available from this work, we intend to pursue grant funding to support further development of this product candidate.

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 recrudesce. There is no preventive vaccine or effective immunotherapy for melioidosis. We believe that there is an unmet 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. In Northeast Thailand, which has a high incidence of melioidosis, 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.

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

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements on the clinical development, manufacture and marketing of new drug and biologic products. The FDA, through regulations that implement the Federal Food, Drug, and Cosmetic Act, as amended, or FDCA, and other laws and comparable regulations for other agencies, regulate research and development activities and the testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale, export, import and distribution of such products. The regulatory approval process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including holds on clinical research, civil or criminal fines or other penalties, product recalls, or

seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

Before human clinical testing in the U.S. of a new drug compound or biological product can commence, an Investigational New Drug, or IND, application is required to be submitted to the FDA. The IND application includes results of pre-clinical animal studies evaluating the safety and efficacy of the drug and a detailed description of the clinical investigations to be undertaken.

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

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With certain exceptions, once successful clinical testing is completed, the sponsor can submit a New Drug Application, or NDA, for approval of a drug, or a Biologic License Application, or BLA, for biologics such as vaccines, which will be reviewed, and if successful, approved by the FDA, allowing the product to be marketed. 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 or BLA, 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. For certain drugs intended to treat serious, life-threatening conditions that show great promise in earlier testing, the FDA can also grant conditional approval. However, drug developers are required to study the drug further and verify clinical benefit as part of the conditional approval provision, and the FDA can revoke approval if later testing does not reproduce previous findings. 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 product. 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 FDCA, the Public Health Service Act, the Federal Trade Commission Act, and other federal and state statutes and regulations that govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of drug, biological, medical device and food products. Noncompliance with applicable requirements can result in, among other things, fines, recall or seizure of products, refusal to permit products to be imported into the U.S., refusal of the government to approve product approval applications or to allow the Company to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution. The FDA may also assess civil penalties for violations of the FDCA 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, the Company will still have to establish that the vaccine and countermeasures it is developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the benefit-risk scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be

able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the animal rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and the Company may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the animal rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations.

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Vaccines are approved under the BLA process that exists under the Public Health Service Act. In addition to the greater technical challenges associated with developing biologics, the potential for generic competition is lower 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 higher. 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.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs or biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug or biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track drug or biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the drug or biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. Unique to a fast track product, the FDA may initiate review of sections of a fast track product's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA or BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means the FDA may approve the product based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

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In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

False Claims Laws

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government.

Anti-Kickback Laws

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other.

United States Healthcare Reform

Federal Physician Payments Sunshine Act and its implementing regulations require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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Third-Party Suppliers and Manufacturers

Drug substance and drug product manufacturing is outsourced to qualified suppliers. We do not have manufacturing capabilities/infrastructure and do not intend to develop the capacity to manufacture drug products substances. We have agreements with third-party manufacturers to supply bulk drug substances for our product candidates and with third parties to formulate, package and distribute our product candidates. Our employees include professionals with expertise in pharmaceutical manufacturing development, quality assurance and third party supplier management who oversee work conducted by third-party companies. We believe that we have on hand or can easily obtain sufficient amounts of product candidates to complete our currently contemplated clinical trials. All of the drug substances used in our product candidates currently are manufactured by single suppliers. While we have not experienced any supply disruptions, the number of manufacturers of the drug substances is limited. In the event it is necessary or advisable to acquire supplies from alternative suppliers, assuming commercially reasonable terms could be reached, the challenge would be the efficient transfer of technology and know-how from current manufactures to the new supplier. Formulation and distribution of our finished product candidates also currently are conducted by single suppliers but we believe that alternative sources for these services are readily available on commercially reasonable terms, subject to the efficient transfer of technology and know-how from current suppliers to the new supplier.

All of the current agreements for the supply bulk drug substances for our product candidates and for the formulation or distribution of our product candidates relate solely to the development (including preclinical and clinical) of our product candidates. Under these contracts, our product candidates are manufactured upon our order of a specific quantity. In the event that we obtain marketing approval for a product candidate, we will qualify secondary suppliers for all key manufacturing activities supporting the marketing application.

Marketing and Collaboration

We do not currently have and do not intend to establish any sales and marketing capability, other than to potentially market our biodefense vaccine products directly to government agencies. With respect to other commercialization efforts, we currently intend to seek distribution and other collaboration arrangements for the sales and marketing of any product candidate that is approved. From time to time, we have had and are having strategic discussions with potential collaboration partners for our biodefense vaccine product candidates, although no assurance can be given that we will be able to enter into one or more collaboration agreements for our product candidate on acceptable terms, if at all. 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.

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 Pharmaceuticals, Inc. (“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, the Company has agreed to pay Sigma-Tau: (a) a royalty amount equal to 3% of all net sales of oral BDP made directly by the Company, 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 the Company's 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 the Company and/or a potential partner from the Company's 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.

Competition

Our competitors are pharmaceutical and biotechnology companies, most of whom have considerably greater financial, technical, and marketing resources than we do. Universities and other research institutions, including the U.S. Army Medical Research Institute of Infectious Diseases, also compete in the development of treatment technologies, and we face competition from other companies to acquire rights to those technologies.

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SGX301 Competition

The FDA has approved several treatments for later stages (IIB-IV) of CTCL and/or in conditions that are unresponsive to prior treatment. Two are targeted therapies (Targretin®-caps and Ontak®), two are histone deacetylases inhibitors (Zolina® and Istodax®) and the remaining two are topical therapies (Valchor® and Targretin®-gel). There are currently no FDA approved therapies for the treatment of front-line, early stage (I-IIA) CTCL; however certain topical chemotherapies and topical, radiation, photo and other therapies which are approved for indications other than CTCL are prescribed off-label for the treatment of early stage CTCL. These include psoralen combined with ultraviolet A (UVA) light therapy ("PUVA"); however, PUVA treatments are usually limited to three times per week and 200 times in total due to the potentially carcinogenic side effect. There are other drugs currently in development that may have the potential to be used in early stage (I-IIA) CTCL – one in phase 2 (vorinostat) and others in phase 1. Vorinistat has been approved by the FDA to treat CTCL patients who have conditions that are unresponsive to other therapies. It currently is being studied in a phase 2 trial for the treatment of all stages of CTCL, with an estimated completion date for the phase 2 trial in September 2016.

SGX94/942 Competition

Because SGX94 uses a novel mechanism of action in combating bacterial infections, 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 (from companies such as Celtaxsys Inc., Innaxon Therapeutics and Innate Pharma SA).

There is currently one drug approved for the treatment of oral mucositis in hematological cancer (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 several 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 Cellceutix Corporation, BioAlliance Pharma S.A. and Alder Biopharmaceuticals Inc.) and one in Phase 1 (under development by ActoGenix N.V.). 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.

Oral BDP Competition

There are a number of approved treatments for Crohn's disease and additional compounds are in late-stage development.

Remicade (infliximab) and Humira (adalimumab) are currently approved for the treatment of pediatric Crohn's disease; however, both carry significant Black Box warnings in their labeling for increased risk of serious infection and malignancy, and therefore are approved for treatment of moderate to severe patients. There is one other marketed biologic, Tysabri (natalizumab), in a Phase 2 study for pediatric Crohn's. Entocort (enteric-coated budesonide) also has completed Phase 3 trials in pediatric Crohn's disease.

ThermoVax™ Competition

Multiple groups and companies are working to address the unmet need of vaccine thermostability using a variety of technologies. In addition, other organizations, such as the Bill and Melinda Gates Foundation and PATH, have programs designed to advance technologies to address this need.

Several 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 Ltd. Variation Biotechnologies, Inc. ("VBI") is developing a lipid system (resembling liposomes) to stabilize viral antigens, including virus-like particles (VLPs), and for potential application to a conventional influenza vaccine among others.

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Other approaches involve process variations to freeze-dry live virus vaccines. For example, PaxVax, Inc., is seeking 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 is seeking 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 Ltd.), 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.

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

Vaccines/BioDefense Competition

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

BioThrax® (Anthrax Vaccine Adsorbed or AVA) is an anthrax vaccine 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 has 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.

There are a number of other companies in preclinical and clinical development of protective antigen-based vaccines and therapeutics including Emergent BioSolutions Inc., Pharmathene, Inc., Dynavax Technologies Corporation, Panacea Biotec Ltd., Paxvax Inc., Elusys Therapeutics, Inc., and Pfenex Inc.

Emergent is currently developing an anthrax immune globulin therapeutic based on plasma collected from military personnel who have been vaccinated with BioThrax®, GlaxoSmithKline plc has been approved for an antibody to *Bacillus anthracis,* referred to as Abthrax™ (raxibacumab), 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 U.S. Army Medical Research Institute of Infectious Diseases, the DoD's lead laboratory for medical research to counter biological threats is also developing a ricin vaccine candidate, RVEc™. 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, Inc., Aeolus Pharmaceuticals, Inc., Boulder Biotechnology, Inc., RxBio, Inc., Avaxia Biologics, Inc., Exponential Biotherapies Inc., Osiris Therapeutics, Inc., ImmuneRegen BioSciences, Inc., Neumedicines, Inc., Cellerant Therapeutics, Inc., Onconova Therapeutics, Inc., Araim Pharmaceuticals, Inc., EVA Pharmaceuticals, Terapio Corporation, 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.

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Patents and Other Proprietary Rights

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

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

We have 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 gastrointestinal graft-versus-host disease, respectively. U.S. patent numbers 8,263,582 and 6,096,731 are expected to expire in March 2022 and June 2018, 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. European patents EP 1392321 and EP 2242477 are expected to expire in March 2022 and January 2029.

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. Additionally, we have numerous patent filings currently issued or pending in foreign jurisdictions covering this subject matter, including Australia, Canada, China, Hong Kong, Israel, India, Japan, South Korea and New Zealand.

ThermoVax™ is the subject of U.S. patent 8,444,991 issued on May 21, 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.” The patent application and the corresponding foreign filings for both patents are pending and licensed to us 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. U.S. patent 8,444,991 is expected to expire in December 2031.

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.

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In 2013, we 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, both in the U.S. and abroad. SGX94 was developed pursuant to discoveries made by Professors B. Brett Finlay and Robert Hancock of the University of British Columbia ("UBC"). U.S. patent 8,124,721 is expected to expire in April 2028.

We recently acquired a novel, first-in-class, photodynamic therapy that utilizes safe visible light for activation, which we refer to as SGX301. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. As part of the acquisition, we acquired a license agreement relating to the use of photo-activated hypericin, composition of matter patent for SGX301 (U.S. patent 8,629,302) and additional issued and pending applications, both in the U.S. and abroad. U.S. patent 8,629,302 is expected to expire in June 2032.

In addition to issued and pending patents, we also have "Orphan Drug" designations for SGX301 in the U.S. for CTCL, SGX203 in the U.S. for pediatric Crohn's disease, and OrbeShield™ in the U.S. for GI ARS, 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. ten year post-approval exclusivity provided by Orphan Drug legislation.

Oral BDP License Agreement

On November 24, 1998, the Company, known at the time as Enteron Pharmaceuticals, Inc. ("Enteron") and George B. McDonald ("Dr. McDonald") entered into an exclusive license agreement for the rights to intellectual property, including know-how, relating to oral BDP. The Company has an exclusive license to commercially exploit the covered products worldwide, subject to Dr. McDonald's right to make and use the technology for research purposes and the U.S. Government's right to use the technology for government purposes. Pursuant to the license agreement, as amended, the Company is required to (i) reimburse Dr. McDonald for certain out-of-pocket expenses incurred by Dr. McDonald in connection with the patent applications and issued patents, (ii) pay Dr. McDonald $400,000 upon approval by the FDA of the Company's first NDA incorporating oral BDP; (iii) pay Dr. McDonald royalty payments equal to 3% of net sales of the covered products and (iv) pay Dr. McDonald $400,000 in cash upon an approval of oral BDP by the European Medicines Agency.

Additionally, in the event that the Company sublicenses its rights under the license agreement, the Company will be required to pay Dr. McDonald 10% of any sublicense fees and royalty payments paid by the sublicense to the

Company.

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

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

SGX94 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, Soligenix 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.

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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 21, 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. U.S. Patent 8,444,991 is expected to expire in December 2031. The license agreement also covers thermostable vaccines for biodefense as well as other potential vaccine indications. In addition, Soligenix in conjunction with UC, filed domestic and foreign patent applications claiming priority back to a provisional application filed on May 17, 2011 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 from UTSW for the nasal, pulmonary and oral uses of a non-toxic ricin vaccine. In July 2003, 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™. UTSW has initiated discussions with us with respect to the continuation of our license to the technology relating to RiVax™.

VeloThrax™ License Option Agreement

On March 5, 2013, 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.

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 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 $1.5 million 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.

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SGX301 License Agreement

In September 2014, we acquired a worldwide exclusive license agreement with New York University and Yeda Research and Development Company Ltd. for the rights to a novel, first-in-class, photodynamic therapy that utilizes safe visible light for activation, which we refer to as SGX301. Our license obligates us to pay $25,000 in annual license fees. In addition, we will pay the licensors: (a) a royalty amount equal to 3% of all net sales of SGX301 made directly by us and/or any affiliates; (b) a royalty amount equal to 2.5% of all net sales of SGX301 made by our sublicensees, subject to stated maximums and (b) 20% of all payments, not based on net sales, received by us from our sublicensees. The exclusive license includes rights to several issued U.S. patents, including U.S. patent numbers 6,867,235 and 7,122,518, among other domestic and foreign patent applications. U.S. Patent numbers 6,867,235 and 7,122,518 are expected to expire in January 2020 and November 2023, respectively.

We acquired the license agreement for SGX301 and related intangible assets, properties and rights pursuant to asset purchase agreement with Hy Biopharma Inc. (“Hy Biopharma”). As consideration for the assets acquired, we paid $250,000 in cash and issued 1,849,113 shares of common stock with a market value of $3,750,000. Provided all future success-orientated milestones are attained, we will be required to make payments of up to $10.0 million, if and when achieved, payable in common stock of the Company.

Research and Development Expenditure

We spent approximately $9.1 million and $5.1 million in the years ended December 31, 2014 and 2013, respectively, and approximately $1.0 million and $1.0 million during the three months ended March 31, 2015 and 2014, respectively on research and development. The amounts we spent on research and development per product during the years ended December 31, 2014, and 2013, and the three months ended March 31, 2015 and 2014, are set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” beginning on page 28 of this prospectus.

Employees

As of March 31, 2015, we had 17 full-time employees, seven of whom are MDs/PhDs.

Properties

We currently lease approximately 5,200 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. In December 2014, we entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months is approximately $12,300 per month, or approximately $20.85 per square foot. This rent increases to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months, and thereafter to approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease. Our office space is sufficient to satisfy our current needs.

Legal Proceedings

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

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MANAGEMENT

The table below contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of July 28, 2015:

Name	Age	Position
Christopher J. Schaber, PhD	48	Chairman of the Board, Chief Executive Officer and President
Keith L. Brownlie, CPA	63	Director
Marco M. Brughera, DVM	60	Director
Gregg A. Lapointe, CPA	56	Director
Robert J. Rubin, MD	69	Director
Jerome Zeldis, MD, PhD	65	Director
Oreola Donini, PhD	43	Chief Scientific Officer and Senior Vice President
Richard Straube, MD	63	Chief Medical Officer and Senior Vice President
Joseph M. Warusz, CPA	59	Vice President of Finance, Acting Chief Financial Officer and Corporate Secretary

Christopher J. Schaber, PhD has over 25 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 has served on the board of directors of the Biotechnology Council of New Jersey ("BioNJ") since January 2009 and the Alliance for Biosecurity since October 2014, and has been 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. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his BA degree from Western Maryland College, his MS degree in Pharmaceutics from Temple University School of Pharmacy and his PhD degree in Pharmaceutical Sciences from the Union Graduate School. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as an executive senior officer with our Company and Discovery Laboratories, Inc., and as a member of the board of directors of BioNJ; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

Keith L. Brownlie, CPA has been a director since June 2011. Mr. Brownlie currently serves on the Board of Directors of Rxi Pharmaceuticals Corporation, a publicly traded biotechnology company involved in the research and development of RNAi products for the diagnosis, prevention and treatment of human diseases, a position he has held

since June 2012. From July 2013 until December 2014, Mr. Brownlie served on the Board of Directors 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. 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 publicly traded specialty pharmaceutical and biotechnology companies.

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Marco Brughera, DVM joined the Board of Directors in October 2013. He is the Global Head of the Rare Disease Franchise for Sigma-Tau S.p.A., a position he has held since October 2012. From December 2011 through January 2014, Dr. Brughera served on the Board of Directors of Gentium S.p.A., a publicly traded biopharmaceutical company. 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 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 Sciences S.r.l. ("NMS Group"), a pharmaceutical oncology-focused integrated discovery and development company. He also served as the Managing Director at Accelera, S.r.l., an independent contract research organization affiliated with the NMS Group. 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. Pursuant to our February 11, 2009 stock purchase agreement with Sigma-Tau Pharmaceuticals, Inc., as long as Sigma-Tau beneficially owns at least 10% of our issued and outstanding shares of common stock, we are required to use our best efforts to secure the election of a Sigma-Tau designee to our Board of Directors. In view of Dr. Brughera's background in the areas of drug discovery and development and his experience as an executive officer and a director in the pharmaceutical industry, the Nominating Committee accepted Dr. Brughera as Sigma-Tau's designee for election to the Board of Directors.

Gregg Lapointe, CPA, MBA 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., Cambrooke Therapeutics, Inc., Raptor Pharmaceuticals, Inc., and the Board of Trustees of the Keck Graduate Institute of Applied Life Sciences. He has previously served on the Board of Directors of the Pharmaceuticals Research and Manufacturers of America (PhRMA) and Questcor Pharmaceuticals, Inc., and has been a member of the Corporate Council of NORD for several years. He previously served in varying roles for Sigma-Tau Pharmaceuticals, Inc., a private biopharmaceutical company, from September 2001 through February 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 World Firm. 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. 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 and medical products industries.

Robert J. Rubin, MD has been a director since October 2009. Dr. Rubin was a clinical professor of medicine at Georgetown University from 1995 until 2012 when he was appointed a Distinguished Professor of Medicine. From 1987 to 2001, he was president of the Lewin Group (purchased by Quintiles Transnational Corp. in 1996), an international health policy and management consulting firm. From 1994 to 1996, Dr. Rubin served as Medical Director of ValueRx, a pharmaceutical benefits company. From 1992 to 1996, Dr. Rubin served as President of Lewin-VHI, a health care consulting company. From 1987 to 1992, he served as President of Lewin-ICF, a health care

consulting company. From 1984 to 1987, Dr. Rubin served as a principal of ICF, Inc., a health care consulting company. From 1981 to 1984, Dr. Rubin served as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services and as an Assistant Surgeon General in the United States 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.

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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, Inc. and Alliqua, Inc. 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 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. 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.

Oreola Donini, PhD, has been with our company since August 15, 2013 and is currently our Chief Scientific Officer and Senior Vice President, a position she has held since December 5, 2014. Dr. Donini served as our Vice President of Preclinical Research and Development from August 15, 2013 until December 4, 2014. She has more than 15 years' experience in drug discovery and preclinical development with start-up biotechnology companies. From 2012 to 2013, Dr. Donini worked with ESSA Pharma Inc. as Vice President Research and Development. From 2004 to 2012, Dr. Donini worked with Inimex Pharmaceuticals Inc., ("Inimex"), lastly as Senior Director of Preclinical R&D from 2007-2013. Prior to joining Inimex, she worked with Kinetek Pharmaceuticals Inc., developing therapies for infectious disease, cancer and cancer supportive care. Dr. Donini is a co-inventor and leader of the Company's SGX94 innate defense regulator technology, developed by Inimex and subsequently acquired by the Company. She was responsible for overseeing the manufacturing and preclinical testing of SGX94, which demonstrated efficacy in combating bacterial infections and mitigating the effects of tissue damage due to trauma, infection, radiation and/or chemotherapy treatment. These preclinical studies resulted in a successful Phase 1 clinical study and clearance of Phase 2 protocols for oral mucositis in head and neck cancer and acute bacterial skin and skin structure infections. While with ESSA Pharma Inc. as the Vice President of Research and Development, Dr. Donini led the preclinical testing of a novel N-terminal domain inhibitor of the androgen receptor for the treatment of prostate cancer. While with Kinetek Pharmaceuticals Inc., her work related to the discovery of novel kinase and phosphatase inhibitors for the treatment of cancer. Dr. Donini received her PhD from Queen's University in Kinston, Ontario, Canada and completed her post-doctoral work at the University of California, San Francisco. Her research has spanned drug discovery, preclinical development, manufacturing and clinical development in infectious disease, cancer and cancer supportive care.

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. From 2009 until joining our company, he was Chief Medical Officer of Stealth Peptides Incorporated, a privately-held, clinical stage, biopharmaceutical company. 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. 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.

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Joseph M. Warusz, CPA has been with the company since June 2011 and is currently our Vice President of Finance and Acting Chief Financial Officer, a position he has held since February 2012. He 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. from 2004 to 2005, Orchid Cellmark, Inc. from 2000 to 2004, and NexMed, Inc. from 1998 to 1999. From 2005 to 2011, Mr. Warusz performed consulting assignments at Ardea BioSciences, Inc., NovaDel Pharma, Inc. and Melior Discovery, all R&D-focused companies in the biotechnology and specialty pharmaceuticals arenas. Prior to 1998, Mr. Warusz also held management positions in financial analysis, accounting, reporting and auditing at Bristol-Myers Squibb and Peat Marwick Main & Company. He received his BS in accounting and MBA in finance at Drexel University and is a Certified Public Accountant.

Board Leadership Structure

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

Messrs. Brownlie and Lapointe, Dr. Rubin, and Dr. Zeldis are independent and the Board of Directors believes that the independent directors provide effective oversight of management. Moreover, in addition to feedback provided during the course of meetings of the Board of Directors, the independent directors hold executive sessions. Following an executive session of independent directors, the independent directors' report back to the full Board of Directors regarding any specific feedback or issues, 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. The Board of Directors believes that this approach appropriately and effectively complements the combined Chairman/Chief Executive Officer structure.

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

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 The NASDAQ Stock Market LLC (“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.

Committees of the Board of Directors

Our Board of Directors has the following three committees: (1) Compensation, (2) Audit and (3) Nominating and Corporate Governance. Our Board of Directors has adopted a written charter for each of these committees, which are available on our website at www.soligenix.com under the “Investors” section.

Director	**Audit Committee**	**Compensation Committee**	**Nominating and Corporate Governance Committee**
Keith L. Brownlie, CPA			
Marco M. Brughera, DVM			
Gregg A. Lapointe, CPA			
Robert J. Rubin, MD			
Jerome Zeldis, MD, PhD			

– Committee Chair
– Member

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Compensation Committee

Our Board of Directors has a Compensation Committee, which is comprised of Dr. Rubin (Chair), Dr. Brughera and Dr. Zeldis. The Compensation Committee is responsible for reviewing and approving the executive compensation program, assessing executive performance, setting salary, making grants of annual incentive compensation and approving certain employment agreements. Our Board of Directors has determined that Dr. Rubin and Dr. Zeldis are "independent" directors within the meaning of applicable listing standards of Nasdaq and the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the rules and regulations thereunder. Our Board of Directors reviewed Dr. Brughera's relationship as the Global Head of the Rare Disease Franchise for Sigma-Tau SpA., an affiliate of Sigma-Tau Pharmaceuticals, Inc., which is owns approximately 13.72% of the issued and outstanding shares of our common stock. Our Board of Directors determined that Dr. Brughera's position with Sigma-Tau SpA. would not impair his ability to exercise independent judgment.

Nominating and Corporate Governance Committee

Our Board of Directors has a Nominating and Corporate Governance Committee ("Nominating Committee"), which is comprised of Dr. Zeldis (Chair), Mr. Brownlie and Mr. Lapointe. The Nominating Committee makes recommendations to the Board of Directors regarding the size and composition of our Board of Directors, establishes procedures for the nomination process, identifies and recommends candidates for election to our Board of Directors. Our Board of Directors has determined that Dr. Zeldis, Mr. Brownlie and Mr. Lapointe are "independent" directors, as such term is defined by the applicable Nasdaq listing standards.

Audit Committee

Our Board of Directors has an Audit Committee, which is comprised of Mr. Brownlie (Chair), Mr. Lapointe and Dr. Rubin. The Audit Committee assists our Board of Directors in monitoring the financial reporting process, the internal control structure and the independent registered public accountants. Its primary duties are to serve as an independent and objective party to monitor the financial reporting process and internal control system, to review and appraise the audit effort of the independent registered public accountants and to provide an open avenue of communication among the independent registered public accountants, financial and senior management, and our Board of Directors. Our Board of Directors has determined that Mr. Brownlie, Mr. Lapointe and Dr. Rubin are "independent" directors, within the meaning of applicable listing standards of Nasdaq and the Exchange Act and the rules and regulations thereunder. Our Board of Directors has also determined that the members of the Audit Committee are qualified to serve on the committee and have the experience and knowledge to perform the duties required of the committee and that Mr. Brownlie qualifies as an "audit committee financial expert" as that term is defined in the applicable regulations of the Exchange Act.

Code of Ethics

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

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Diversity Considerations in Identifying Director Nominees

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

Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee is or has at any time during the past year been one of our officers or employees. None of our executive officers currently serves or in the past year has served as a member of the Board of Directors or Compensation Committee of any entity that has one or more executive officers serving on our Board of Directors or Compensation Committee.

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 under the "Investors" section.

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EXECUTIVE COMPENSATION

Summary Compensation

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2014 to our Chief Executive Officer and each of the two other most highly compensated executive officers during 2014 (collectively, the "Named Executive Officers").

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber [1]	CEO & President	2014	$412,000	$115,000	$150,000	$ 29,580	$706,580
		2013	$402,000	$239,000	$199,000	$ 33,896	$873,896
Joseph M. Warusz [2]	VP & Acting CFO	2014	$191,000	$41,000	$67,500	$ 21,197	$320,697
		2013	$186,000	$90,000	$89,550	$ 32,641	$398,191
Richard C. Straube [3]	CMO & Senior VP	2014	$300,000	$62,000	$276,000	$ 21,328	$659,328

[1] Dr. Schaber deferred the payment of his 2014 bonus of $115,000 until January 15, 2015. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

[2] Mr. Warusz deferred the payment of his 2014 bonus of $41,000 until January 15, 2015. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

[3] Dr. Straube joined the Company on January 1, 2014. He deferred the payment of his 2014 bonus of $62,000 until January 15, 2015. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

Employment and Severance Agreements

In August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, PhD. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of $300,000 per year and a minimum annual bonus of $100,000. Dr. Schaber's 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 the Company due to merger or acquisition, all of Dr. Schaber's options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during 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. Dr. Schaber's employment agreement automatically renewed in December 2013 for an additional term of three years.

On June 22, 2011, the Compensation Committee eliminated his fixed minimum annual bonus payable and revised it to an annual targeted bonus of 40% of his annual base salary. On December 6, 2012, the Compensation Committee approved an increase in salary for Dr. Schaber to $402,000. On December 4, 2013, the Compensation Committee approved an increase in salary for Dr. Schaber to $412,000. On December 4, 2014, the Compensation Committee approved an increase in salary for Dr. Schaber to $424,360

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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 Mr. Warusz’s employment 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 an increase in salary for Mr. Warusz to $186,000 and the targeted annual bonus to 35%. On December 4, 2013, the Compensation Committee approved an increase in salary for Mr. Warusz to $191,000. On December 4, 2014, the Compensation Committee approved an increase in salary for Mr. Warusz to $196,730.

In December 2014, we entered into a one-year employment agreement with Richard C. Straube, MD, our Chief Medical Officer and Senior Vice President. Pursuant to the agreement, we have agreed to pay Dr. Straube $300,000 per year and a targeted annual bonus of 30% of base salary. We also agreed to issue him options to purchase 100,000 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 Dr. Straube’s employment agreement, we would pay Dr. Straube three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 4, 2014, the Compensation Committee approved an increase in salary for Dr. Straube to $309,000.

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

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Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2014. We have never issued Stock Appreciation Rights.

Name	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned	Option Exercise	Option Expiration
	Exercisable	Unexercisable	Options (#)	Price ($)	Date
Christopher J. Schaber	125,000	-	-	$ 5.40	8/28/2016
	45,000	-	-	$ 9.40	8/9/2017
	140,000	-	-	$ 1.20	12/17/2018
	110,000	-	-	$ 4.64	6/30/2020
	112,185	-	-	$ 0.64	11/30/2021
	97,500	32,500	32,500	$ 0.68	12/04/2022
	50,000	50,000	50,000	$ 2.01	12/04/2023
	25,000	75,000	75,000	$ 1.50	12/04/2024
Richard C. Straube	43,750	56,250	56,250	$ 2.01	1/06/2024
	12,500	37,500	37,500	$ 1.50	12/04/2024
Joseph M. Warusz	40,000	-	-	$ 4.10	5/30/2021
	25,310	-	-	$ 0.64	11/30/2021
	41,254	13,746	13,746	$ 0.68	12/04/2022
	22,502	22,498	22,498	$ 2.01	12/04/2023
	11,250	33,750	33,750	$ 1.50	12/04/2024

Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2014.

Name	Fees Earned Paid in Cash [1]	Option Awards [2]	Total
Keith Brownlie	$57,500	$30,000	$87,500
Marco Brughera	$37,500	$30,000	$67,500
Gregg A. Lapointe	$47,500	$30,000	$77,500
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 director who is not a full-time employee is paid $35,000 annually, on a prorated basis, for his service on our Board of Directors, the chair of our Audit Committee is paid $15,000 annually, on a prorated basis, and the chairs of our Compensation and Nominating Committees are 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, 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 member will receive stock options to purchase up to 25,000 shares of common stock, not to exceed a value of $30,000 (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.

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CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Our audit committee is responsible for the review, approval and ratification of related party transactions. The audit committee reviews these transactions under our Code of Ethics, which governs conflicts of interests, among other matters, and is applicable to our employees, officers and directors.

Other than the employment agreements and compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2014.

PRINCIPAL STOCKHOLDERS

The table below provides information regarding the beneficial ownership of the common stock as of July 28, 2015, of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Beneficial Ownership

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percent of Class
Randall J. Kirk (1)	6,867,816	23.78 %
NRM VII Holdings I, LLC (1)	5,833,333	20.20 %
Paolo Cavazza (2)	3,379,950	12.60 %
Sigma-Tau Pharmaceuticals, Inc. (2)	3,068,461	11.48 %
Hy Biopharma, Inc. (3)	1,608,354	6.10 %
Intrexon Corporation (1)	1,034,483	3.92 %
Christopher J. Schaber (4)	854,423	3.15 %
Keith Brownlie (5)	100,307	*

Marco Brughera (6)	28,699	*	
Gregg A. Lapointe (7)	165,860	*	
Robert J. Rubin (8)	103,574	*	
Jerry Zeldis (9)	108,640	*	
Joseph Warusz (10)	185,422	*	
Richard Straube (11)	84,375	*	
All directors and executive officers as a group (8 persons)	1,738,175	6.24	%

(1) On June 26, 2013, Randal J. Kirk, on his own behalf and on behalf of Third Security, LLC, NRM 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 July 28, 2015 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.

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(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 87,804 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 July 28, 2015 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) On October 3, 2014, Hy BioPharma, Inc. filed a Schedule 13G with the SEC (the "Schedule 13G"). The Schedule 13G indicates that Hy Biopharma, Inc. has sole voting and dispositive power with respect to shares of common stock held by it. The address of the principal business office of Hy BioPharma, Inc. is 2500 York Road, #100, Jamison, Pennsylvania 18929.

(4) Includes 82,904 shares of common stock, options to purchase 766,560 shares of common stock exercisable within 60 days of July 28, 2015, and warrants to purchase 4,959 shares of common stock exercisable within 60 days of July 28, 2015. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(5) Includes 50,000 shares of common stock and options to purchase 50,307 shares of common stock exercisable within 60 days of the July 28, 2015. The address of Mr. Brownlie is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(6) Includes 7,500 shares of common stock, options to purchase 21,199 shares of common stock exercisable within 60 days of July 28, 2015. The address of Dr. Brughera is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540**.**

(7) Includes 48,781 shares of common stock, options to purchase 87,811 shares of common stock exercisable within 60 days of July 28, 2015, and warrants to purchase 29,268 shares of common stock exercisable within 60 days of July 28, 2015. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(8) Includes 12,196 shares of common stock, options to purchase 84,061 shares of common stock exercisable within 60 days of July 28, 2015, and warrants to purchase 7,317 shares of common stock exercisable within 60 days of July 28, 2015. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

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(9) Includes 66,666 shares of common stock and options to purchase 41,974 shares of common stock exercisable within 60 days of July 28, 2015. The address of Dr. Zeldis is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

(10) Includes 12,955 shares of common stock, options to purchase 167,508 shares of common stock owned by Mr. Warusz exercisable within 60 days of July 28, 2015 and warrants to purchase 4,959 shares of common stock exercisable within 60 days of July 28, 2015. The address of Mr. Warusz is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540**.**

(11) Includes options to purchase 84,375 shares of common stock exercisable within 60 days of July 28, 2015. The address of Dr. Straube is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540**.**

* Indicates less than 1%.

** Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of July 28, 2015 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 26,381,976 shares of common stock outstanding as of July 28, 2015.

THE EQUITY PURCHASE TRANSACTIONS

General

On July 29, 2015, we entered into the Purchase Agreements and the Registration Rights Agreements with the Equity Purchasers. Pursuant to the terms of the Purchase Agreements, the Equity Purchasers have agreed to purchase from us up to $10 million in the aggregate worth of our common stock from time to time, until December 31, 2016. Pursuant to the terms of the Registration Rights Agreements, we have filed with 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 may be issued to the Equity Purchasers under the Purchase Agreements.

We do not have the right to commence any sales to the Equity Purchasers under the Purchase Agreements 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 the Equity Purchasers to purchase shares of our common stock. The purchase price per share will be equal to 80% of the lowest daily volume weighted average price of the common stock for the five consecutive trading days immediately following our request for the Equity Purchasers to purchase the shares. In consideration for entering into the Purchase Agreements, we issued to each of the Equity Purchasers a promissory note having a principal amount equal to 3% of the total amount committed by it, which are payable on April 15, 2016.

Purchase of Shares Under the Purchase Agreements

Under the Purchase Agreements, we may direct Kodiak Capital, Kingsbrook and River North to purchase, on a pro rata bases, up to $5 million, $4 million and $1 million of shares of our common stock, respectively. The closing of the sale of the shares will occur on the sixth trading day following our request for the Equity Purchasers to purchase the shares. The purchase price per share will be equal to 80% of the lowest daily volume weighted average price of the common stock for the five consecutive trading days immediately following our request for the Equity Purchasers to purchase the shares. There is no minimum amount that we may require the Equity Purchasers to purchase at any one time. We may not require the Equity Purchasers to purchase more than $3 million worth of shares of common stock during any seven day period.

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

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Conditions to Sales

Under the Purchase Agreements, the following conditions must be satisfied in order for us to sell shares of our common stock to the Equity Purchasers:

The registration statement of which this prospectus forms a part, and any amendment or supplement thereto, must be effective for the sale by the Equity Purchaser of the shares to be purchased by the Equity Purchaser, and (i) neither we nor the Equity Purchaser have received notice that the SEC has issued or intends to issue a stop order with respect to the registration statement or that the SEC otherwise has suspended or withdrawn the effectiveness of the registration statement, either temporarily or permanently, or intends or has threatened to do so and (ii) there is no other suspension of the use or withdrawal of the effectiveness of the registration statement or this prospectus.

Our representations and warranties contained in the Purchase Agreements must be true and correct in all material respects (except for representations and warranties specifically made as of a particular date), except for any conditions that have temporarily caused any representations or warranties to be incorrect and which have been corrected with no continuing impairment to us or the Equity Purchaser.

We must have performed in all material respects all covenants, agreements and conditions required by the Purchase Agreements to be performed, satisfied or complied with by us.

No statute, rule, regulation, executive order, decree, ruling or injunction has been enacted, entered, promulgated or adopted by any court or governmental authority of competent jurisdiction that prohibits or directly and materially adversely affects any of the transactions contemplated by the Purchase Agreements, and no proceeding has been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by the Purchase Agreements.

The trading of our common stock has not been suspended by the SEC, the principal trading market for our common stock or Financial Industry Regulatory Authority, Inc. and our common stock has been approved for listing or quotation on and has not been delisted from such principal market.

The number of shares of our common stock to be purchased by the Equity Purchaser at a particular closing may not exceed the number of shares that, when aggregated with all other shares of common stock then beneficially owned by such Equity Purchaser, would result in the Equity Purchaser owning more than 9.99% of all of our outstanding common stock.

We must have no knowledge of any event more likely than not to have the effect of causing the registration statement of which this prospectus forms a part to be suspended or otherwise ineffective.

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 the Equity Purchasers to terminate the Purchase Agreements.

No Short-Selling by the Equity Purchasers

The Equity Purchasers have agreed that neither they nor any of their respective affiliates shall engage in any direct or indirect short-selling of our common stock during any time prior to the termination of the Purchase Agreements.

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Effect of Performance of the Purchase Agreements 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 commencing on the date that the registration statement including this prospectus becomes effective through December 31, 2016. The sale by the Equity Purchasers 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. The Equity Purchasers 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 the Equity Purchasers, the Equity Purchasers may sell all, some or none of such shares. Therefore, sales to the Equity Purchasers by us under the Purchase Agreements 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 the Equity Purchasers under the Purchase Agreements, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with the Equity Purchasers 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 the Equity Purchasers and the Purchase Agreements may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreements, we have the right, but not the obligation, to direct Kodiak Capital, Kingsbrook and River North to purchase up to $5 million, $4 million and $1 million of our common stock, respectively. Depending on the price per share at which we sell our common stock to the Equity Purchasers, we may be authorized to issue and sell to the Equity Purchasers under the Purchase Agreements 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 the Equity Purchasers under this prospectus is dependent upon the number of shares we direct the Equity Purchasers to purchase under the Purchase Agreements.

The following table sets forth the amount of proceeds we would receive from the Equity Purchasers from the sale of shares at varying purchase prices:

Assumed Average Purchase Price Per Share	Number of Registered Shares to be Issued if	Percentage of Outstanding Shares After Giving Effect to	Additional Proceeds from the Sale of Registered Shares Under the

		Full Purchase (1)	the Issuance (2)		Purchase Agreement
$ 0.50		7,627,120	22.43	%	$3,813,560
$ 1.00		7,627,120	22.43	%	$7,627,120
$ 1.376	(3)	7,267,441	21.60	%	$10,000,000
$ 2.00		5,000,000	15.93	%	$10,000,000
$ 2.50		4,000,000	13.17	%	$10,000,000

(1) Although the Purchase Agreements with the Equity Purchasers provides that we may sell up $10 million of our common stock to the Equity Purchasers in the aggregate, we are only registering 7,627,120 shares for resale by the Equity Purchasers under this prospectus, which may or may not cover all the shares we ultimately sell to the Equity Purchasers under the Purchase Agreements, 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.

(2) The denominator is based on 26,381,976 shares outstanding as of July 28, 2015, and is adjusted to include the number of shares set forth in the adjacent column which we would have sold to Kodiak Capital at the applicable assumed purchase price per share. The numerator is based on the number of shares issuable under the Purchase Agreements at the corresponding assumed purchase price set forth in the adjacent column. The number of shares in such column does not include shares that may be issued to the Equity Purchasers under the Purchase Agreements which are not registered in this offering.

(3) $1.376 is 80% of the closing price of the common stock on July 28, 2015.

SELLING STOCKHOLDERS

This prospectus relates to the possible resale by the selling stockholders, including 7,627,120 shares of common stock that may be issued to the Equity Purchasers pursuant to the Purchase Agreements. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the agreements executed in connection with the selling stockholders' agreement to purchase the shares.

Pursuant to the Registration Rights Agreements, which we entered into with the Equity Purchasers on July 29, 2015 concurrently with our execution of the Purchase Agreements, we agreed to provide certain registration rights with respect to sales by the Equity Purchasers of the shares of our common stock that may be issued to the Equity Purchasers under the Purchase Agreements. See the description under the heading "The Equity Purchase Transactions" for more information about the Purchase Agreements.

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On April 27, 2013, we entered into the Channel Agreement with Intrexon to use Intrexon's advanced human antibody discovery, isolation and production technologies for the development of human monoclonal antibody therapies for a biodefense application targeting melioidosis. The Channel Agreement granted 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. The Channel Agreement, upon clinical or commercialization success, may require the payment of certain milestones payments up to $7 million, if and when achieved. Also on April 27, 2013, we entered into a stock issuance agreement (the "Stock Issuance Agreement") with Intrexon, pursuant to which we issued to Intrexon 1,034,483 shares of common stock in consideration for the execution and delivery of the Channel Agreement. Pursuant to the Stock Issuance Agreement, we agreed to provide certain registration rights with respect to sales by Intrexon of the shares of our common stock. Additionally, as part of our June 2013 public offering, we sold to NRM VII Holdings I, LLC, an affiliate of Intrexon, 3,333,333 shares of common stock and a warrant to purchase 2,500,000 shares of common stock for an aggregate purchase price of approximately $3.5 million.

The selling stockholders, 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 them. The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares.

The following table presents information regarding the selling stockholders and the shares that they may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the selling stockholders, and reflects their holdings as of July 28, 2015. Except as described herein, none of the selling stockholders nor any of their respective 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 stockholders" includes the selling stockholders and any of their respective donees, pledgees, transferees or other successors in interest selling shares received after the date of this prospectus from the selling stockholders 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 26,381,976 shares of our common stock actually outstanding as of July 28, 2015.

Selling stockholders	**Shares Beneficially Owned Before this Offering**	**Percentage of Outstanding Shares Beneficially Owned Before this Offering (5)**	**Shares to be Sold in this Offering**	**Number Of Shares Beneficially Owned After this Offering**	**Percentage of Outstanding Shares Beneficially Owned After this Offering**
Kodiak Capital Group, LLC (1)	--	*	3,389,831 (6)	—	*
Kingsbrook Opportunities Master Fund LP (2)	--	*	3,389,831 (7)	—	*

River North Equity, LLC (3)	--	*	847,458 (8)	—	*
Intrexon Corporation (4)	1,034,483	3.92 %	1,034,483	—	*

***Less than 1%**

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(1) Ryan Hodson exercises voting and dispositive power with respect to the shares of our common stock being offered under this prospectus by Kodiak Capital.

(2) Ari Storch, Adam J. Chill and Scott Wallace, in their capacities as managing members of the general partner of Kingsbrook, exercise voting and dispositive power with respect to the shares of our common stock being offered under this prospectus by Kingsbrook.

(3) Edward M. Liceaga exercises voting and dispositive power with respect to the shares of our common stock being offered under this prospectus by River North.

(4) Randall J. Kirk exercises voting and dispositive power with respect to the shares of our common stock being offered under this prospectus by Intrexon.

(5) Based on 26,381,976 outstanding shares of our common stock as of July 28, 2015. Although we may at our discretion elect to issue to the Equity Purchasers up to an aggregate amount of $10 million of our common stock under the Purchase Agreements, such shares are not included in determining the percentage of shares beneficially owned before this offering.

(6) Assumes issuance of the maximum 3,389,831 shares being registered hereby.

(7) Assumes issuance of the maximum 3,389,831 shares being registered hereby.

(8) Assumes issuance of the maximum 847,458 shares being registered hereby.

PLAN OF DISTRIBUTION

The Equity Purchasers are “underwriters,” and the other selling stockholders may be deemed to be an “underwriter,” within the meaning of the Securities Act. The selling stockholders and any of their respective pledgees, donees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock being offered under this prospectus on any stock exchange, market or trading facility on which shares of our common stock are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when disposing of shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resales by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

broker-dealers may agree with the selling stockholder to sell a specified number of such shares at a stipulated price per share;

a combination of any of these methods of sale; and

any other method permitted pursuant to applicable law.

The shares may also be sold under Rule 144 under the Securities Act, if available, rather than under this prospectus. The selling stockholders have the sole and absolute discretion not to accept any purchase offer or make any sale of shares if such selling stockholder deems the purchase price to be unsatisfactory at any particular time.

The selling stockholders may pledge their respective shares to their brokers under the margin provisions of customer agreements. If any selling stockholder defaults on a margin loan, the broker may, from time to time, offer and sell the pledged shares.

After the effective date of the registration statement, the selling stockholders, other than the Equity Purchasers, may engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities and may sell or deliver shares in connection with these trades. The Equity Purchasers have agreed not to engage in any direct or indirect short selling of our common stock during the term of the Purchase Agreements.

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Broker-dealers engaged by a selling stockholder may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from a selling stockholder (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, which commissions as to a particular broker or dealer may be in excess of customary commissions to the extent permitted by applicable law.

If sales of shares offered under this prospectus are made to broker-dealers as principals, we would be required to file a post-effective amendment to the registration statement of which this prospectus is a part. In the post-effective amendment, we would be required to disclose the names of any participating broker-dealers and the compensation arrangements relating to such sales.

The Equity Purchasers are “underwriters,” and the other selling stockholders and any broker-dealers or agents that are involved in selling the shares offered under this prospectus may be deemed to be "underwriters," within the meaning of the Securities Act in connection with these sales. Commissions received by these broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Any broker-dealers or agents that are deemed to be underwriters may not sell shares offered under this prospectus unless and until we set forth the names of the underwriters and the material details of their underwriting arrangements in a supplement to this prospectus or, if required, in a replacement prospectus included in a post-effective amendment to the registration statement of which this prospectus is a part.

The selling stockholders and any other persons participating in the sale or distribution of the shares offered under this prospectus will be subject to applicable provisions of the Exchange Act and the rules and regulations under that act, including Regulation M. These provisions may restrict activities of and limit the timing of purchases and sales of any of the shares by the selling stockholders or any other person. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and other activities with respect to those securities for a specified period of time prior to the commencement of such distributions, subject to specified exceptions or exemptions. All of these limitations may affect the marketability of the shares.

If any of the shares of common stock offered for sale pursuant to this prospectus are transferred other than pursuant to a sale under this prospectus, then subsequent holders could not use this prospectus until a post-effective amendment or prospectus supplement is filed, naming such holders. We offer no assurance as to whether the selling stockholders will sell all or any portion of the shares offered under this prospectus.

We have agreed to pay all fees and expenses we incur incident to the registration of the shares being offered under this prospectus. However, each selling security holder and purchaser are responsible for paying any discounts, commissions and similar selling expenses they incur.

The selling stockholders and the issuer have agreed to indemnify one another against certain losses, damages and liabilities arising in connection with this prospectus, including liabilities under the Securities Act. Under the securities laws of certain states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. The selling stockholders are advised to ensure that any brokers, dealers or agents effecting transactions on behalf of the selling stockholders are registered to sell securities in all fifty states. In addition, in certain states the shares of common stock may not be sold unless the shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

We will pay all the expenses incident to the registration, offering and sale of the shares of common stock to the public hereunder other than commissions, fees and discounts of brokers, dealers and agents. We estimate that the expenses of the offering to be borne by us will be approximately $78,500. The estimated offering expenses consist of: an SEC registration fee of $1,737, accounting fees of $10,000, legal fees of $65,000 and miscellaneous expenses of $1,763. We will not receive any proceeds from the sale of any of the shares of common stock by the selling stockholders.

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The selling stockholders should be aware that the anti-manipulation provisions of Regulation M under the Exchange Act will apply to purchases and sales of shares of common stock by the selling stockholders, and that there are restrictions on market-making activities by persons engaged in the distribution of the shares. Under Regulation M, the selling stockholders or its agents may not bid for, purchase, or attempt to induce any person to bid for or purchase, shares of our common stock of while such selling stockholders is distributing shares covered by this prospectus. The selling stockholders is advised that if a particular offer of common stock is to be made on terms constituting a material change from the information set forth above with respect to this Plan of Distribution, then, to the extent required, a post-effective amendment to the accompanying registration statement must be filed with the SEC.

Blue Sky Restrictions on Resale

If a selling stockholder wants to sell shares of our common stock under this registration statement in the United States, the selling stockholder will also need to comply with state securities laws, also known as “Blue Sky laws,” with regard to secondary sales. All states offer a variety of exemption from registration for secondary sales. Many states, for example, have an exemption for secondary trading of securities registered under Section 12(g) of the Exchange Act or for securities of issuers that publish continuous disclosure of financial and non-financial information in a recognized securities manual, such as Standard & Poor’s. The broker for the selling stockholder will be able to advise the selling stockholder which states our common stock is exempt from registration with that state for secondary sales.

Any person who purchases shares of our common stock from a selling stockholder under this registration statement who then wants to sell such shares will also have to comply with Blue Sky laws regarding secondary sales.

When the registration statement becomes effective, and the selling stockholders indicate in which state(s) they desire to sell their shares, we will be able to identify whether it will need to register or will rely on an exemption therefrom.

DESCRIPTION OF CAPITAL STOCK

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 July 28, 2015, there were issued and outstanding 26,381,976 shares of common stock, options to purchase 2,338,237 shares of common stock and warrants to purchase 4,941,119 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.

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

Series B Preferred Stock

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

Voting

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

Dividends

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

Conversion

Each share of Series B Cumulative Convertible Preferred is 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.

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Junior Preferred Stock

Voting

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

Dividends

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

Liquidation

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

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.

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

Warrants

On June 25, 2013, we consummated a public offering of an aggregate of 6,773,995 shares of common stock, together with warrants to purchase up to 5,080,500 shares of common stock. In connection with the offering, we also issued the placement agent a warrant to purchase up to 336,081 shares of common stock. We refer to the warrants issued to the investors and the placement agent in connection with the offering as the "2013 Warrants."

As a result of exercises, 3,036,928 shares of common stock remain issuable upon the exercise of the 2013 Warrants as of July 28, 2015. The 2013 Warrants expire in June 2018.

As of July 28, 2015, the 2013 Warrants were exercisable to purchase shares of common stock a $0.61. per share. The 2013 Warrants include a price protection provision pursuant to which, in the event, and on each such occasion on or before the expiration of the 2013 Warrants, we issue any shares of common stock or convertible securities (other than shares issued or issuable in certain transactions, including upon exercise of employee stock options, upon conversion or exercise of currently-outstanding convertible securities, or in connection with acquisitions or strategic transactions) at a price less than the then current exercise price (a "Dilutive Issuance"), the exercise price of the 2013 Warrants will automatically be reduced to a price equal to the price at which such shares were issued and sold in the Dilutive Issuance. Additionally, the exercise price and the number of shares of common stock purchasable upon the exercise of each 2013 Warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

On December 24, 2014, we consummated a public offering of an aggregate of 1,886,530 shares of common stock, together with warrants to purchase up to 1,131,918 shares of common stock. In connection with the offering, we also issued the underwriter a warrant to purchase up to 37,400 shares of common stock. We refer to the warrants issued to the investors and the placement agent in connection with the offering as the "2014 Warrants."

As of July 28, 2015, 1,109,318 shares of common stock remain issuable upon the exercise of the 2014 Warrants, which expire in 2019.

As of July 28, 2015, we also had other outstanding warrants to purchase 794,873 shares of common stock, all of which are exercisable at a weighted average exercise price of approximately $0.65 per share.

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."

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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.

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.

EXPERTS

The consolidated balance sheets of Soligenix, Inc. as of December 31, 2014 and 2013 and the related consolidated statements of operations, changes in shareholders' deficiency, and cash flows for each of the years in the two-year period ended December 31, 2014, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is included herein. Such financial statements have been included herein in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE 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 shares 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 shares offered 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.

The representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were made as of an earlier date. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

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.

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

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SOLIGENIX, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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Soligenix, Inc. and Subsidiaries

Consolidated Balance Sheets

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	**$5,012,605**	$5,525,094
Contracts and grants receivable	**345,420**	794,767
Prepaid expenses	**131,546**	172,928
Total current assets	**5,489,571**	6,492,789
Office furniture and equipment, net	**57,176**	51,510
Intangible assets, net	**355,910**	409,949
Total assets	**$5,902,657**	$6,954,248
Liabilities and shareholders' deficiency		
Current liabilities:		
Accounts payable	**$2,543,942**	$3,003,545
Warrant liability	**5,152,367**	3,789,562
Accrued compensation	**32,189**	315,030
Total current liabilities	**7,728,498**	7,108,137
Commitments and contingencies		
Shareholders' deficiency:		
Preferred stock; 350,000 shares authorized; none issued or outstanding	**-**	-
Common stock, $.001 par value; 50,000,000 shares authorized; 25,339,364 shares and 23,936,568 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	**25,340**	23,937
Additional paid-in capital	**141,764,490**	138,868,523
Accumulated deficit	**(143,615,671)**	(139,046,349)
Total shareholders' deficiency	**(1,825,841)**	(153,889)
Total liabilities and shareholders' deficiency	**$5,902,657**	$6,954,248

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

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Soligenix, Inc. and Subsidiaries

Consolidated Statements of Operations

For the Three Months Ended March 31, 2015 and 2014

(Unaudited)

	Three Months Ended	
	March 31, 2015	2014
Revenues:		
Grant revenue	**$103,880**	$244,290
Contract revenue	**712,406**	666,307
Total revenues	**816,286**	910,597
Cost of revenues	**(527,399)**	(628,981)
Gross profit	**288,887**	281,616
Operating expenses:		
Research and development	**1,029,884**	1,030,621
General and administrative	**817,270**	840,904
Total operating expenses	**1,847,154**	1,871,525
Loss from operations	**(1,558,267)**	(1,589,909)
Other income (expense):		
Change in fair value of warrant liability	**(3,011,616)**	(1,742,090)
Interest income	**561**	291
Total other income (expense)	**(3,011,055)**	(1,741,799)