SOLIGENIX, INC.
Form S-1/A
August 21, 2015

**As filed with the Securities and Exchange Commission on August 21, 2015.**

**Registration No. 333-206055**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**AMENDMENT NO. 1**

**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 |

**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 21, 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 August 19, 2015, the last quoted sale price of our common stock as reported on the OTCQB was $1.23 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;<br><br>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;<br><br>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;<br><br>safety and preliminary efficacy demonstrated;<br><br>Phase 2 trial planned for the first half of 2016,<br><br>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;<br>Phase 1/2 trial planned for the second half of 2015 |
| VeloThrax™ | Vaccine against Anthrax Poisoning | Pre-clinical;<br>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 August 19, 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 August 19, 2015, 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 August 19, 2015. 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 |
| | 4,926,119 shares of common stock issuable upon exercise of outstanding warrants as of the date of this prospectus with a weighted average exercise price of $0.80 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 June 30, 2015, had an accumulated deficit of approximately $147.6 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of June 30, 2015, we had approximately $4.0 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 June 2015, we have expended approximately $63.3 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least $15.0 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 $9.7 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 August 19, 2015, the last quoted sale price of our common stock as reported on the OTCQB was $1.23 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 June 30, 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 4,948,262 shares of our common stock at a current weighted average exercise price of approximately $0.81; and

- options to purchase approximately 2,338,237 shares of our common stock at a current weighted average exercise price of approximately $2.31.

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 August 19, 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 August 19, 2015) | $ 2.48 | $ 1.13 |

On August 19, 2015, the last reported price of our common stock quoted on the OTCQB was $1.23 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 August 19, 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 August 19, 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 June 30, 2015, we had a negative net tangible book value of $(3,820,489), or approximately $(0.14) 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 $1.23 (the closing price of our common stock on August 19, 2015) and the pro forma as adjusted net tangible book value per share of common stock immediately after the sale of the 7,627,120 shares of common stock being registered for resale to the Equity Purchasers under the Purchase Agreements. Therefore, after giving effect to our assumed receipt of $7,121,433.50 in estimated net proceeds from the issuance of 7,627,120 shares of common stock under the Purchase Agreements (which is the number of shares being registered for resale to the Equity Purchasers hereunder) and registered in this offering (assuming a purchase price of $0.984 per share, 80% of the closing price of the common stock on August 19, 2015, and assuming such sale was made on June 30, 2015, and after deducting estimated offering commissions and expenses payable by us), our pro forma as adjusted net tangible book value as of June 30, 2015 would have been $3,300,944, or $0.10 per share. This would represent an immediate increase in the net tangible book value of $0.24 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 | | $ 1.23 |
| Net tangible book value per share as of June 30, 2015 | $ (0.14 ) | |
| Increase in as adjusted net tangible book value per share attributable to the sale of shares under the Purchase Agreements | 0.24 | |
| Pro forma net tangible book value per share after the sale of shares under the Purchase Agreements | | 0.10 |
| Dilution per share to new investors | | $ 1.13 |

To the extent that we sell more or less than $7,121,433.50 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 $0.984, then the dilution reflected in the table above will differ. The above table is based on 26,374,833 shares of our common stock outstanding as of June 30, 2015, adjusted for the assumed sale of $7,121,433.50 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 26,374,833 shares of our common stock outstanding as of June 30, 2015 and excludes, as of that date:

2,338,237 shares issuable upon exercise of outstanding options with a weighted average exercise price of $2.31;

4,948,262 shares issuable upon exercise of outstanding warrants with a weighted average exercise price of $0.81; and

329,397 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 and Six Months Ended June 30, 2015 Compared to June 30, 2014***

For the three months ended June 30, 2015, we had a net loss of $3,977,694 as compared to a net loss of $948,517 for the same period in the prior year, representing an increase in the net loss of $3,029,177 or 319%. For the six months ended June 30, 2015, we had a net loss of $8,547,016 as compared to a net loss of $4,280,225 for the same period in the prior year, representing an increase of $4,266,791 or 100%. Included in the net loss for the three months and six months ended June 30, 2015 is the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public financing. The change in the fair value of the warrant liability for the three months ended June 30, 2015 and 2014 was ($1,943,494) expense, and $746,992 income, respectively. For the six months ended June 30, 2015 and 2014, the change in fair value was ($4,955,110) and ($995,098) respectively.

For the three and six months ended June 30, 2015, revenues relate to government contracts and grants awarded in support of our development of OrbeShield™ for the treatment of GI ARS and RiVax™, and other development programs. For the three months ended June 30, 2015, we had revenues of $1,099,827 as compared to $1,418,248 for the same period in the prior year, representing a decrease of $318,421 or 22%. For the six months ended June 30, 2015, we had revenues of $1,916,113 as compared to $2,328,845 for the same period in the prior year, representing a decrease of $412,732 or 18%. The decrease in revenues was primarily related to our ThermoVax™ grant expiring during the fourth quarter of 2014.

We incurred costs related to those revenues for the three months ended June 30, 2015 and 2014 of $816,702 and $1,034,584, respectively, representing a decrease of $217,882, or 21%. For the six months ended June 30, 2015, costs related to revenues were $1,344,101 as compared to $1,663,565 for the same period in the prior year, representing a decrease of $319,464 or 19%. 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 June 30, 2015 was $283,125 as compared to $383,664 for the same period in 2014, representing a decrease of $100,539 or 26 %. For the six months ended June 30, 2015, gross profit was $572,012 as compared to $665,280 for the same period in the prior year representing a decrease of $93,268 or 14%. The decrease is primarily due to the reduction in revenue related to our ThermoVax™ grant expiring during the fourth quarter of 2014.

Research and development expenses increased by $229,690 or 19%, to $1,442,914 for the three months ended June 30, 2015 as compared to $1,213,224 for the same period in 2014. For the six months ended June 30, 2015, research

and development expenses were $2,472,798 compared to $2,243,845 for the same period in 2014, reflecting an increase of $228,953 or 10%. This increase for the three and six months ended June 30, 2015 was due to the manufacture of clinical supplies to support the Phase 3 trial of SGX301 for the treatment of CTCL.

General and administrative expenses increased by $8,691 or 1%, to $874,962 for the three months ended June 30, 2015 as compared to $866,271 for the same period in 2014. For the six months ended June 30, 2015, general and administrative expenses were $1,692,232 compared to $1,707,175, reflecting a decrease of $14,943 or 1%.

Other income (expense) for the three months ended June 30, 2015 was ($1,942,943) as compared $747,314 for the same period in 2014, reflecting a change of ($2,690,257). For the six months ended June 30, 2015 and 2014, other (expense) was ($4,953,998) and ($994,485), respectively, reflecting a change of ($3,959,513). The change in both the three and six months ended June 30, 2015 is primarily due to 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, oral and 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 June 30, 2015, we had cash and cash equivalents of $4,035,578 as compared to $5,525,094 as of December 31, 2014, representing a decrease of $1,489,516 or 27%. As of June 30, 2015, we had working capital of $2,328,147 which excludes a non-cash warrant liability of $6,201,555, as compared to working capital of $3,174,214, which excludes a non-cash warrant liability of $3,789,562, as of December 31, 2014, representing a decrease of $846,067 or 27%. The 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 and manufacture of clinical supplies to support the Phase 3 trial of SGX301 for the treatment of CTCL.

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 from the date of this filing.

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

We have up to approximately $49.5 million in active contract and grant funding still available to support our associated research programs through 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 $8.4 million is available as of June 30, 2015.

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 its 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.

***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 $15.0 million before any grant reimbursements, of which $5.3 million relates to the BioTherapeutics business and $9.7 million relates to the Vaccines/BioDefense business. We anticipate contract and grant revenues in the next 12 months of approximately $9.7 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 six months ended June 30, 2015 and 2014:

| | **Years Ended December 31,** | | **Six Months Ended June 30,** | |
|---|---|---|---|---|
| | **2014** | **2013** | **2015** | 2014 |
| ***Research & Development Expenses*** | | | | |
| Oral BDP | $ 561,655 | $ 1,467,077 | **$ -** | $ 698,193 |
| RiVax™ & ThermoVax™ Vaccines | 846,870 | 1,113,430 | **176,219** | 257,128 |
| SGX94 | 2,820,807 | 659,809 | **1,116,234** | 1,158,368 |
| SGX943/101 | 19,378 | 1,500,000 | **10,671** | - |
| SGX301 | 4,369,585 | - | **1,024,153** | - |
| Other | 468,240 | 330,863 | **145,521** | 130,156 |
| Total | $ 9,086,535 | $ 5,071,179 | **$ 2,472,798** | $ 2,243,845 |
| ***Reimbursed under Government Contracts and Grants*** | | | | |
| Oral BDP | $ 4,100,663 | $ 672,194 | **$ 959,627** | $ 1,257,927 |
| RiVax™ & ThermoVax™ Vaccines | 930,573 | 1,872,091 | **303,397** | 309,109 |
| Other | 282,619 | - | **81,077** | 96,529 |
| Total | $ 5,313,855 | $ 2,544,285 | **$ 1,344,101** | $ 1,663,565 |
| Grand Total | $ 14,400,390 | $ 7,615,464 | **$ 3,816,899** | $ 3,907,410 |

***Contractual Obligations***

We have commitments of approximately $500,000 as of June 30, 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 certain milestone 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 issue such shares if such event occurs.

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

| Year | Research and Development | Property and Other Leases | Total |
|---|---|---|---|
| July 1 through December 31, 2015 | $ 100,000 | $ 78,000 | $ 178,000 |
| 2016 | 100,000 | 157,000 | 257,000 |
| 2017 | 100,000 | 152,000 | 252,000 |
| 2018 | 100,000 | 52,000 | 152,000 |
| 2019 | 100,000 | - | 100,000 |
| Total | $ 500,000 | $ 439,000 | $ 939,000 |

**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;<br><br>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;<br><br>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;<br><br>safety and preliminary efficacy demonstrated;<br><br>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;<br>Phase 1/2 trial planned for the second half of 2015 |
| VeloThrax™ | Vaccine against Anthrax Poisoning | Pre-clinical;<br>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 $\leq 0.04$) 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.