SOLIGENIX, INC.
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Registration No. 333-221681

PROSPECTUS

SOLIGENIX, INC.

982,000 SHARES OF COMMON STOCK

This prospectus relates to the sale from time to time of up to 982,000 shares of our common stock by the selling stockholders named in this prospectus in the section "Selling Stockholders," including their pledgees, assignees and successors-in-interest, whom we collectively refer to in this document as the "Selling Stockholders."

The shares of common stock being offered by the Selling Stockholders were issued pursuant to the securities purchase agreement dated November 2, 2017, pursuant to which we issued, in a private placement, to the Selling Stockholders an aggregate of 982,000 shares of our common stock. In a concurrent public offering, we issued an aggregate of 1,575,500 shares of our common stock, including 1,320,500 shares issued to the Selling Stockholders or their affiliates. In connection with the private placement and the public offering, we issued the placement agent warrants to purchase up to 51,150 shares of our common stock as partial payment of placement agent fees. Neither the warrants issued to the placement agent nor the shares underlying such warrants are being offered for sale by this prospectus. The common stock offered by this prospectus shall be adjusted to cover any additional securities as may become issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions.

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

The Selling Stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See "Plan of Distribution" beginning on page 70 for more information about how the Selling Stockholders may sell the shares of common stock being registered pursuant to this prospectus.

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 and our common stock warrant issued in connection with our December 2016 public offering are traded on The Nasdaq Capital Market under the symbols "SNGX" and "SNGXW," respectively. On November 15, 2017, the last reported closing sales prices of our common stock and our common stock warrant issued in connection with our 2016 public offering on The Nasdaq Capital Market were $2.20 per share and $0.61 per warrant.

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

Our business and an investment in our securities involves significant risks, including those set forth in the "Risk Factors" section of this prospectus beginning on page 4.

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 November 30, 2017

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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 units in any jurisdiction where the offer is not permitted.

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

PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. For a more complete understanding of this offering, you should read the entire prospectus carefully, including the risk factors and the financial statements and related notes before making an investment decision. 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 focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible florescent light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and 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).

Our Vaccines/BioDefense business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the 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 have advanced the development of OrbeShield® for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from the NIAID.

An outline of our business strategy follows:

Complete enrollment and report preliminary results in our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;

Continue site initiation and enrollment of the pivotal Phase 3 trial of SGX942 for the treatment of oral mucositis in head and neck cancer patients;

Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease contingent upon additional funding, such as through partnership and/or government funding support;

Continue development of RiVax® in combination with our ThermoVax® technology to develop new heat stable vaccines in biodefense with NIAID funding support;

Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS contingent upon government funding support;

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

Pursue business development opportunities for our pipeline programs, as well as explore merger/acquisition strategies; and

Acquire or in-license new clinical-stage compounds for development.

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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 compared to placebo; Phase 3 clinical trial initiated in December 2015, with data expected in the second half of 2018
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial initiated July 2017, with data expected in the first half of 2019
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed; efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety profile demonstrated; Phase 3 clinical trial planned for the first half of 2018, with data expected in the second half of 2019
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial completed; safety profile and preliminary efficacy demonstrated

Vaccine Thermostability Platform**

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

BioDefense Products**

Soligenix Product Candidate	Indication	Stage of Development
RiVax®	Vaccine against Ricin Toxin Poisoning	Phase 1b trial complete, safety and neutralizing antibodies for protection demonstrated; Phase 1/2 trial planned for the first half of 2018
OrbeShield®	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943	Therapeutic against Infectious Diseases	Pre-clinical

*** Contingent upon continued government contract/grant funding or other funding source.*

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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 B-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

The Offering

This prospectus relates to the offer and sale, from time to time, of up to 982,000 shares of our common stock by the Selling Stockholders, all of which are currently issued and outstanding. We are also registering for sale any additional shares of common stock that may become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock.

The Selling Stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See "Plan of Distribution" beginning on page 70 for more information about how the Selling Stockholders may sell the shares of common stock being registered pursuant to this prospectus.

We will not receive any proceeds from the sale of shares by the Selling Stockholders.

As of November 15, 2017, there were 8,730,640 shares issued and outstanding, including the 982,000 shares of our common stock offered by the Selling Stockholders pursuant to this prospectus. The number of shares offered by this prospectus represents approximately 11.3% of the total common stock outstanding as of November 15, 2017.

Securities Offered

Common Stock offered by the Selling Stockholders	982,000 shares.
	8,730,640 shares, as of November 15, 2017.

Common stock outstanding immediately prior to and after the offering	
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. See “Use of Proceeds.”
Risk factors	In analyzing an investment in the shares of common stock being offered pursuant to this prospectus, you should carefully consider, along with other matters included in this prospectus, the information set forth under “Risk Factors” in this prospectus.
Nasdaq Capital Market symbol	Our common stock and our common stock warrant issued in connection with our December 2016 public offering are listed on The Nasdaq Capital Market under the symbols “SNGX” and “SNGXW,” respectively.

The number of shares of common stock to be outstanding after this offering is based on 8,730,640 shares of common stock outstanding on November 15, 2017, includes the 982,000 shares of our common stock offered by the Selling Stockholders pursuant to this prospectus and excludes:

- 510,055 shares of common stock issuable upon the exercise of outstanding options at a weighted average exercise price of $9.93 per share, of which 339,609 options are vested as of November 15, 2017;
- 2,654,725 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $4.41 per share, of which 2,570,175 warrants are exercisable as of November 15, 2017; and
- 289,569 shares of our common stock available for future issuance under our 2015 Equity Incentive Plan as of November 15, 2017.

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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 September 30, 2017, had an accumulated deficit of approximately $155.1 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of September 30, 2017, we had approximately $5.0 million in cash and cash equivalents available. Based on our projected budgetary needs, funding from existing contracts and grants over the next two years, sales to the purchasers under our existing equity lines, and sales in the private placement and the concurrent public offering in November 2017, we expect to be able to maintain the current level of our operations through at least December 31, 2018.

In September 2014, we entered into a contract with the National Institutes of Health ("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 over six years if options to extend the contract are exercised by the NIH. In September 2013, we entered into contracts with NIAID 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. We have received approximately $18 million in combined BARDA and NIH contract funding for the development of OrbeShield®. We have completed the contract with NIAID and the BARDA contract base period, with BARDA electing not to extend the contract. In addition, we were awarded two separate grants from the NIH of approximately $1.5 million each to support of our pivotal Phase 3 trials of SGX301 for the treatment of Cutaneous T-Cell Lymphoma and SGX942 for the treatment of Oral Mucositis in head and neck cancer. 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. We have approximately $20.6 million in awarded contract and grant funding, assuming the NIAID options are exercised for the development of RiVax®. BARDA has elected

not to fund the additional options remaining under the contract.

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 September 30, 2017, we have expended approximately $74.1 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend approximately $10.5 million over the 12 month period from September 30, 2017 in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements, of which approximately $5.5 million is expected to be reimbursed through our existing government contracts and grants.

We have no control over the resources and funding NIH, BARDA and NIAID may devote to our programs, which may be subject to periodic renewal and which generally may be terminated by the government at any time for convenience. Any significant reductions in the funding of U.S. government agencies or in the funding areas targeted by our business could materially and adversely affect our biodefense program and our results of operations and financial condition. If we fail to satisfy our obligations under the government contracts, the applicable Federal Acquisition Regulations allow the government to terminate the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the government any incomplete work. If NIH, BARDA or NIAID do not exercise future funding options under the contracts or grants, terminate the funding or fail to perform their responsibilities under the agreements or grants, it could materially impact our biodefense program and our financial results.

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Unless and until we are able to generate sales or licensing revenue from one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs.

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

In order to generate revenues and profits, our organization must, along with corporate partners and collaborators, positively research, develop 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.

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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 to supply or manufacture our products;
- our dependence on contract research organizations 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.

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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 contracts and 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 United States 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.

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.

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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 and contract documents and other regulations. We can provide no assurance that

we will receive or continue to receive funding for grants and contracts we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business.

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

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

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We rely on third parties for pre-clinical and clinical trials of our product candidates and, in some cases, to maintain regulatory files for our product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

We rely on academic institutions, hospitals, clinics and other third-party collaborators for preclinical and clinical trials of our product candidates. Although we monitor, support, and/or oversee our pre-clinical and clinical trials, because we do not conduct these trials ourselves, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then preclinical and/or clinical trials of our product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or regulatory agencies.

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.

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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.

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.

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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.

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;

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- 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.

If we fail to obtain or maintain orphan drug exclusivity for our product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Medicines Agency's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have orphan drug designation for SGX301 in the United States and Europe, and SGX203, RiVax® and OrbeShield® in the United States, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing drugs or biologic products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Absent patent or other intellectual property protection, even after an orphan drug is approved, the FDA or European Medicines Agency may subsequently approve the same drug with the same active moiety for the same condition if the FDA or European Medicines Agency concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

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.

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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. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, if at all. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates. See “Business - Patents and Other Proprietary Rights” for a description of our license agreements.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

the sublicensing of patent and other rights;

our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and

the priority of invention of patented technology.

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If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Additionally, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

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 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.

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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.

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.

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

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

During recent years, there has been substantial volatility in financial markets due at least in part to the uncertainty with regard to the global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by 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.

We may not be able to utilize all of our net operating loss carryforwards.

The State of New Jersey's Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused net operating loss ("NOL") carryforwards to other New Jersey-based corporate taxpayers. In accordance with this program, during the year ended December 31, 2016, we sold New Jersey NOL carryforwards, resulting in the recognition of $530,143 of income tax benefit. If there is an unfavorable change in the State of New Jersey's Technology Business Tax Certificate Program (whether as a result of a change in law, policy or otherwise) that terminates the program or eliminates or reduces our ability to use or sell our NOL carryforwards, our cash taxes may increase which may have an adverse effect on our financial condition.

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.

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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.

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.

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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.

Risks Related to our Securities

The price of our common stock and warrants may be 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 the price of our common stock may be volatile 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;

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- economic and other external factors;
- failure of our common stock or warrants to be listed or quoted on The Nasdaq Stock Market, NYSE Amex Equities or other national market system; and
- general market conditions.

Since January 1, 2016, the closing stock price (split adjusted) of our common stock has fluctuated between a high of $12.50 per share to a low of $1.84 per share. On November 15, 2017, the last reported closing sales price of our common stock on The Nasdaq Capital Market was $2.20 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 us, 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.

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

As of November 15, 2017, we had a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximately 2,654,725 shares of our common stock at a current weighted average exercise price of approximately $4.41; and
- options to purchase approximately 510,055 shares of our common stock at a current weighted average exercise price of approximately $9.93.

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.

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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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.

The sale or issuance of our common stock pursuant to an at the market offering agreement with FBR Capital Markets & Co. may cause dilution and the sale of the shares of common stock sold pursuant to the at the market offering agreement, or the perception that such sales may occur, could cause the price of our common stock to fall.

On August 11, 2017, we entered into an At Market Issuance Sales Agreement (the "Sales Agreement") with FBR Capital Markets & Co. ("FBR") to sell shares of our common stock, with aggregate gross proceeds of up to $4,800,000, from time to time, through an "at-the-market" equity offering program under which FBR will act as sales agent. From August 11, 2017 through November 15, 2017, we sold 450,000 shares under the Sales Agreement and received gross proceeds of $1,015,266.

Under the Sales Agreement, we will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, FBR may sell the shares by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on or through The Nasdaq Capital Market, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. The Sales Agreement provides that FBR will be entitled to

compensation for its services in an amount equal to 3% of the gross proceeds from the sale of shares sold under the Sales Agreement.

Depending on market liquidity at the time, sales of shares under the Sales Agreement may cause the trading price of our common stock to fall. Additionally, further sales of our common stock, if any, under the Sales Agreement will depend upon market conditions and other factors to be determined by us. We ultimately may sell all, some or none of the shares of our common stock that may be sold pursuant to the Sales Agreement and, after such shares have been sold, the purchasers may sell all, some or none of those shares. Therefore, sales under the Sales Agreement 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 under the Sales Agreement, 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 sale or issuance of our common stock to Lincoln Park Capital 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 March 22, 2016, we entered into an additional purchase agreement (the "2016 Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the 2016 Purchase Agreement, Lincoln Park has committed to purchase up to $12 million of our common stock, of which approximately $10.2 million worth of our common stock remains issuable as of November 15, 2017. Concurrently with the execution of the 2016 Purchase Agreement, we issued 10,000 shares of our common stock to Lincoln Park as a partial fee for its commitment to purchase shares of our common stock under the 2016 Purchase Agreement. From March 22, 2016 through November 15, 2017, we sold 310,000 shares to Lincoln Park and issued 7,618 additional shares to Lincoln Park as additional commitment shares under the 2016 Purchase Agreement and received proceeds of $1,828,250. The shares that may be sold pursuant to the 2016 Purchase Agreement may be sold by us to Lincoln Park at our sole discretion from time to time over the remaining term of approximately 16 months from November 15, 2017, provided the registration statement registering the resale of shares sold to Lincoln Park under the 2016 Purchase Agreement remains effective. The purchase price for the shares that we may sell to Lincoln Park under the 2016 Purchase Agreement will fluctuate based on the price of our common stock. We 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 that would cause Lincoln Park to beneficially own more than 4.99% of our issued and outstanding common stock.

Depending on market liquidity at the time, sales of shares under the 2016 Purchase Agreement may cause the trading price of our common stock to fall. Additionally, further sales of our common stock, if any, to Lincoln Park under the 2016 Purchase Agreement will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the 2016 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 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 4,307 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 $275,000 in cash and issued 184,912 shares of common stock in the aggregate to Hy Biopharma and its assignees, and the licensors of the license agreement acquired from Hy Biopharma, 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. The next milestone payment will be payable if the Phase 3 clinical trial of SGX301 is successful in demonstrating efficacy and safety in the CTCL patient population. Also on September 3, 2014, we entered into a Registration Rights Agreement with Hy Biopharma, pursuant to which we have filed a registration statement with the Securities and Exchange Commission (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 AND

INDUSTRY DATA AND MARKET INFORMATION

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act. These forward-looking statements are often identified by words such as “may,” “should,” “would,” “expect,” “intend,” “anticipate,” “believe,” “estimate,” “continue,” “plan,” “potential” and similar expressio 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 (the “FDA”) 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;

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- 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.

You should also consider carefully the statements under “Risk Factors” in this prospectus and Sections entitled “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, 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 and grants 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: (1) 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; (2) any FDA approval of the product candidate may contain restrictions on its use or require warning labels; (3) third party payors may not be willing to provide reimbursement for the product candidate at the assumed price per patient; (4) the government may not be willing to procure our vaccine candidates in amounts or at costs similar to its historic procurement activities; (5) the dosage that ultimately may be approved may be different from the assumed dosage; and (6) 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.

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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.

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 traded on The Nasdaq Capital Market under the symbol “SNGX”. The following table sets forth, as adjusted for the reverse stock split of one-for-ten effective October 7, 2016, for the periods indicated, the high and low sales prices per share of our common stock as reported by the OTCQB through December 12, 2016 and The Nasdaq Capital Market, beginning on December 13, 2016.

	Price Range	
Period	High	Low
Year Ended December 31, 2015:		
First Quarter	$23.00	$9.80
Second Quarter	$29.50	$13.60
Third Quarter	$24.80	$9.10
Fourth Quarter	$14.40	$4.40
Year Ended December 31, 2016:		
First Quarter	$12.50	$6.20
Second Quarter	$9.00	$6.20
Third Quarter	$8.50	$5.60
Fourth Quarter	$8.11	$2.05

Year Ending December 31, 2017:		
First Quarter	$3.18	$1.90
Second Quarter	$5.08	$2.00
Third Quarter	$2.99	$1.98
Fourth Quarter (through November 15, 2017)	$2.61	$1.74

On November 15, 2017, the last reported price of our common stock quoted on The Nasdaq Capital Market was $2.20 per share. The Nasdaq 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.

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On December 13, 2016, our common stock warrant issued in connection with our December 2016 public offering began trading on The Nasdaq Capital Market under the symbol “SNGXW”. For the period December 13, 2016 through November 15, 2017, the high and low sales price per warrant as reported by Nasdaq were $1.3144 and $0.2109, respectively. On November 15, 2017, the last reported price of our common stock warrant on Nasdaq was $0.61 per warrant.

Transfer Agent

The transfer agent and registrar for our common stock and warrants is American Stock Transfer & Trust Company, LLC. The address is 6201 15th Avenue, Brooklyn, NY 11219 and the telephone number is (718) 921-8200.

Holders of Common Stock

As of November 15, 2017, there were 87 holders of record of our common stock. As of such date, 8,730,640 shares of our common stock were issued and outstanding.

Equity Compensation Plan Information

In December 2005, our Board of Directors approved the 2005 Equity Incentive Plan, which was approved by stockholders on December 29, 2005. In September 2013, 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 125,000 shares, bringing the total shares reserved for issuance under the plan to 300,000 shares. In April 2015, our Board of Directors approved the 2015 Equity Incentive Plan, which was approved by stockholders on June 18, 2015. As of June 8, 2017, a maximum of 600,000 shares of our common stock are available for issuance under the 2015 Equity Incentive Plan. The following table provides information, as of December 31, 2016 with respect to options outstanding under our 2005 Equity Incentive Plan and our 2015 Equity Incentive Plan. All share numbers in this paragraph and in the following table have been adjusted for the one-for-ten reverse stock split effective October 7, 2016.

Plan Category	**Number of Securities to be Issued upon**	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	**Number of Securities Remaining Available for Future**

	Exercise of Outstanding Options, Warrants and Rights		**Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)**
Equity compensation plans approved by security holders (1)	330,605	$ 17.07	185,769
Equity compensation plans not approved by security holders	-	-	-
Total	330,605	$ 17.07	185,769

(1) Includes our 2005 Equity Incentive Plan and our 2015 Equity Incentive Plan. Our 2005 Plan expired in 2015 and thus no securities remain available for future issuance under that plan.

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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 and Industry Data and Market Information."

Our Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible florescent light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and 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).

Our Vaccines/BioDefense business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the 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 have advanced the development of OrbeShield® for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from the NIAID.

An outline of our business strategy follows:

- Complete enrollment and report preliminary results in our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;
- Continue site initiation and enrollment of the pivotal Phase 3 trial of SGX942 for the treatment of oral mucositis in head and neck cancer patients;
- Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease contingent upon additional funding, such as through partnership and/or government funding support;
- Continue development of RiVax® in combination with our ThermoVax® technology to develop new heat stable vaccines in biodefense with NIAID funding support;

Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS contingent upon government funding support;

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- Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
- Pursue business development opportunities for our pipeline programs, as well as explore merger/acquisition strategies; and
- Acquire or in-license new clinical-stage compounds for development.

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.

Revenue Recognition

Our revenues are primarily generated from government contracts and grants. The revenue from government contracts and grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the contracts and grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fees. These revenues are recognized when expenses have been incurred by subcontractors or when we incur reimbursable internal expenses that are related to the government contracts and grants.

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, share-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.

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 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 were recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. During the year ended December 31, 2016, we entered into amendments with the holders of those warrants, and as a result the warrants were then reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. 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 generally vest 25% on 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.

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From time to time, we issue restricted shares of common stock to vendors and consultants as compensation for services performed. Typically these instruments vest upon issuance and therefore the entire share-based compensation expense is recognized upon issuance to the vendors and/or consultants.

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

The fair value of each option grant made during 2017 and 2016 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option vesting periods, which approximates the service period.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through September 30, 2017 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2017 and 2016. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at September 30, 2017 and December 31, 2016.

Earnings Per Share

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

results for each period presented.

Use of Estimates and Assumptions

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

Material Changes in Results of Operations

Three and Nine Months Ended September 30, 2017 Compared to September 30, 2016

For the three months ended September 30, 2017, we had a net loss of $963,094 as compared to a net loss of $1,673,217 for the same period in the prior year, representing a decrease in the net loss of $710,123 or 42%. For the nine months ended September 30, 2017, we had a net loss of $5,008,129 as compared to a net loss of $2,915,424 for the same period in the prior year, representing an increase in the net loss of $2,092,705 or 72%. Included in the net loss for the three months and nine months ended September 30, 2016 is non-cash expense of $176,293, and non-cash income of $1,109,192, respectively, representing the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public financing, which were reclassified to equity in November 2016.

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For the three and nine months ended September 30, 2017, revenues related to government contracts awarded in support of our development of OrbeShield® for the treatment of GI ARS and RiVax®, our ricin toxin vaccine program, as well as grants awarded in support of our pivotal Phase 3 clinical trials of SGX301, for the treatment of CTCL, and SGX942, for the treatment of oral mucositis in head and neck cancer. For the three months ended September 30, 2017, we had revenues of $1,822,066 as compared to $2,959,254 for the same period in the prior year, representing a decrease of $1,137,188 or 38%. For the nine months ended September 30, 2017, we had revenues of $4,143,921 as compared to $8,750,291 for the same period in the prior year, representing a decrease of $4,606,370 or 53%. The decrease in revenues was a result of the completion of the NIAID contract during the first quarter of 2017, along with the BARDA contract base period, with BARDA electing not to extend the current contract beyond the base period. This was partially offset by an increase in grant revenue for the three months ended September 30, 2017.

We incurred costs related to those revenues for the three months ended September 30, 2017 and 2016 of $1,474,151 and $2,630,046, respectively, representing a decrease of $1,155,895, or 44%. For the nine months ended September 30, 2017, costs related to revenues were $3,238,633 as compared to $7,204,920 for the same period in the prior year, representing a decrease of $3,966,287 or 55%. The decrease in costs was primarily the result of the decrease in revenues from the completion of the NIAID and BARDA contracts.

Our gross profit for the three months ended September 30, 2017 was $347,915 or 19% of revenues, as compared to $329,208 or 11% of revenues for the same period in 2016, representing an increase of $18,707 or 8% of revenues. For the nine months ended September 30, 2017, gross profit was $905,288 or 22% of revenues, as compared to $1,545,371 or 18% of revenues for the same period in 2016, representing a decrease of $640,083. The increase in gross profit percentage of 4% for the nine months ended September 30, 2017, as compared to the same periods in 2016, was primarily attributable to higher amounts of reimbursement in 2017 for certain contractor and employee expenses from contracts and grants, as well as management and administrative fees from the two grants awarded in 2017 in support of our pivotal Phase 3 trials of SGX301 and SGX942.

Research and development expenses were $605,719 for the three months ended September 30, 2017 as compared to $1,177,263 for the same period in 2016, representing a decrease of $571,544 or 49%. For the nine months ended September 30, 2017, research and development expenses were $3,606,973 compared to $3,433,595 for the same period in 2016, representing an increase of $173,378 or 5%. The decrease in research and development spending for the three months ended September 30, 2017 was primarily due to the two grants awarded in which certain research and development expenses are reimbursable under the terms of the grants. As a result, the expenditures for those research and development expenses are recorded in cost of revenues. The increase in research and development spending for the nine months ended September 30, 2017 was related to expenditures incurred in the preparation and initiation of the Phase 3 clinical trial of SGX942 as well as the ongoing Phase 3 clinical trial of SGX301.

General and administrative expenses were $711,819 for the three months ended September 30, 2017 as compared to $650,762 for the same period in 2016, representing an increase of $61,057 or 9%. For the nine months ended September 30, 2017, general and administrative expenses were $2,322,957 compared to $2,526,255, representing a decrease of $203,298 or 8%. The increase in general and administrative expenses for the three months ended

September 30, 2017 is primarily related to an increase in professional consulting fees. The decrease in general and administrative expenses for the nine months ended September 30, 2017 is primarily related to a decrease in our compensation expenses, including stock option expense.

Other income (expense) for the three months ended September 30, 2017 was $6,529 as compared $(174,400) for the same period in 2016, representing an increase in other income of $180,929 or 104%. For the nine months ended September 30, 2017 and 2016, total other income was $16,513 and $1,499,055, respectively, representing a decrease of $1,482,542 or 99%. The change in both the three and nine months ended September 30, 2017 is primarily due to the change in the fair value of the warrant liability for the three and nine months ended September 30, 2016 resulting in $(176,293) and $1,109,192 of other income (expense). In addition, $390,599 was included in other income for the nine months ended September 30, 2016 related to an amount that had previously been accrued. We were notified during the quarter ended June 30, 2016 that the amount was no longer considered outstanding by the counterparty and therefore reversed the amount accrued, resulting in other income.

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Year Ended December 31, 2016 Compared to 2015

For the year ended December 31, 2016, we had a net loss of $3,245,383 as compared to a net loss of $7,831,230 for the prior year, representing a decreased loss of $4,585,847 or 59%. Included in the net loss for December 31, 2016 and 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 of $1,541,241 of other income and $1,201,870 of other expense, respectively. During the year ended December 31, 2016, the price protection provision of the warrants was eliminated through an amendment and the warrant liability was reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments.

For the year ended December 31, 2016 and 2015, revenues and associated costs related 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 year ended December 31, 2016, we had revenues of $10,448,794 as compared to $8,768,390 for the prior year, representing an increase of $1,680,404 or 19%. The increase in revenues was a result of increased activities performed under our government contracts associated with RiVax.™

We incurred costs related to contract and grant revenues in the year ended December 31, 2016 and 2015 of $8,433,671 and $6,882,204, respectively, representing an increase of $1,551,467 or 23%. The costs primarily relate to the increased development activity in these programs and the resulting payments made to subcontractors and the allocated employee costs in connection with research performed pursuant to the contracts and grants.

Our gross profit for the year ended December 31, 2016 was $2,015,123 or 19%, as compared to $1,886,186 or 22% for the prior year, representing an increase of $128,937 or 7%. This increase in gross profit is due primarily to the increased activity in our RiVax™ development contracts. The decrease in gross profit percentage is attributable to the management fee associated with certain contracts payable upon the achievement of development milestones.

Research and development expenses decreased by $1,103,972 or 20%, to $4,295,867 for the year ended December 31, 2016 as compared to $5,399,839 for the prior year. This decrease is primarily related to the manufacturing expenditures for the pediatric Crohn’s development program incurred during 2015, as well as the completion of patient enrollment in the Phase 2 trial of SGX942 for the treatment of oral mucositis in head and neck cancer in late 2015.

General and administrative expenses decreased by $167,785 or 5%, to $3,428,838 for the year ended December 31, 2016, as compared to $3,596,623 for the prior year. This decrease is primarily related to a decrease in professional fees.

Other income (expense) for the year ended December 31, 2016 was $1,934,056 as compared to $(1,209,887) for the prior year, reflecting a change of $3,143,943 or 260%. The change is primarily due to the change in the fair value of the warrant liability resulting in $(1,201,870) of other expense in 2015 compared to $1,541,241 of other income in 2016. In addition, $390,599 is included in other income in 2016 related to an amount that had previously been accrued. We were notified that the amount was no longer considered outstanding by the counterparty and therefore reversed the amount accrued, resulting in other income.

The State of New Jersey's Technology Business Tax Certificate Program allows certain high technology and biotechnology companies to sell unused net operating loss ("NOL") carryforwards to other New Jersey-based corporate taxpayers. In accordance with this program, during the year ended December 31, 2016, we sold New Jersey NOL carryforwards, resulting in the recognition of $530,143 of income tax benefit as compared to $488,933 for the year ended December 31, 2015. There can be no assurance as to the continuation or magnitude of this program in future years.

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Business Segments

We maintain two active business segments for the years ended December 31, 2016 and December 31, 2015: Vaccines/BioDefense and BioTherapeutics.

Revenues for the Vaccines/BioDefense business segment for the year ended December 31, 2016 were $10,448,794 as compared to $8,754,418 for the year ended December 31, 2015, representing an increase of $1,694,376 or 19%. This increase in revenues was a result of the increased development activity under our RiVax™ contracts. Revenues for the BioTherapeutics business segment for the year ended December 31, 2016 were $0 as compared to $13,972 for the year ended December 31, 2015. The revenue for the year ended December 31, 2015 is related to work performed under our oral mucositis grant which expired in early 2015.

Income from operations for the Vaccines/BioDefense business segment for the year ended December 31, 2016 was $1,563,884 as compared to $1,263,709 for the year ended December 31, 2015. 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, 2016 was $3,399,933 as compared to $4,487,988 for the year ended December 31, 2015, representing a decrease of $1,088,055 or 24%. This decreased loss is due primarily to the completion of patient enrollment in the Phase 2 clinical trial of SGX942 in patients suffering from oral mucositis associated with their CRT for head and neck cancer and offset by expenses incurred in the initiation of the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL.

Amortization and depreciation expense for the Vaccines/BioDefense business segment for the year ended December 31, 2016 was $40,186 as compared to $39,925 for the year ended December 31, 2015. Amortization and depreciation expense for the BioTherapeutics business segment for the year ended December 31, 2016 was $41,395 as compared to $199,661 for the year ended December 31, 2015. The $158,266 decrease in amortization and depreciation expense for the BioTherapeutics segment was the result of a license agreement becoming fully amortized during the year ended December 31, 2015 and accordingly, there was no amortization expense recognized during the year ended December 31, 2016 for the license agreement.

Financial Condition and Liquidity

Cash and Working Capital

As of September 30, 2017, we had cash and cash equivalents of $4,999,153 as compared to $8,772,567 as of December 31, 2016, representing a decrease of $3,773,414 or 43%. As of September 30, 2017, we had working capital of $3,047,007 as compared to working capital of $7,243,918 as of December 31, 2016, representing a decrease of $4,196,911 or 58%. The decrease in cash and cash equivalents and working capital is primarily related to expenditures to support the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL and expenditures incurred in the preparation and initiation of the Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer.

Based on our current rate of cash outflows, cash on hand, proceeds from government contract and grant programs, proceeds available from the equity line with Lincoln Park, proceeds remaining from the At-the-Market sale of shares of our common stock with FBR 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.

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

We have up to $20.6 million in active government contract and grant funding still available to support our associated research programs through 2017 and beyond, provided the federal agencies exercise all options and do not elect to terminate the contracts or grants for convenience. We plan to submit additional contract and grant applications for further support of our 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;

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We will pursue Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. We expect to receive $416,809 in net proceeds in 2017 from the sale of the NOL. We expect to participate in the program during 2018 and beyond as long as the program is available;

We plan to pursue potential partnerships for pipeline programs. However, there can be no assurances that we can consummate such transactions;

We have $10.2 million available from an equity facility expiring in March 2019;

We have $4.3 million remaining from the ATM agreement with FBR; and

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 currently evaluating additional equity/debt 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 and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the 12 month period from September 30, 2017 to be approximately $10.5 million before any contract or grant reimbursements, of which $7.0 million relates to the BioTherapeutics business and $3.5 million relates to the Vaccines/BioDefense business. We anticipate contract and grant revenues in the next 12 months of approximately $5.5 million to offset research and development expenses of the Vaccines/BioDefense business segment.

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

	2017	**2016**
Research & Development Expenses		
Oral BDP	$-	$210,038
RiVax® and ThermoVax® Vaccines	339,609	228,274
Dusquetide (SGX942)	1,710,973	1,030,740
SGX943	115	1,628
SGX301	1,213,268	1,559,480
Other	343,008	403,435
Total	3,606,973	3,433,595
Reimbursed under Government Contracts and Grants		
OrbeShield®	171,618	3,254,204

RiVax® and ThermoVax® Vaccines	2,779,728	3,950,365
SGX942	128,186	-
SGX301	159,101	-
Other	-	351
Total	3,238,633	7,204,920
Grand Total	$6,845,606	$10,638,515

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Contractual Obligations

We have commitments of approximately $425,000 as of September 30, 2017 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. As of September 30, 2017, no milestone or royalty payments have been paid or accrued.

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 was approximately $12,300 per month, or approximately $20.85 per square foot. This rent increased to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months, and thereafter increased to approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease. In October 2017, the lease was amended through October 2020. The rent for the first 12 months will be approximately $11,367 per month, or approximately $22.00 per square foot. The rent will increase to approximately $11,625 per month, or approximately $22.50 per square foot, for the next 12 months and increase to approximately $11,883 per month, or approximately $23.00 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 $275,000 in cash and issued 184,912 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 our outstanding stock. As of September 30, 2017, no milestone payments have been made or accrued.

In February 2007, our Board of Directors authorized the issuance of 5,000 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.

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
October 1 through December 31, 2017	$ 25,000	$37,329	$62,329
2018	100,000	138,697	238,697
2019	100,000	140,017	240,017
2020	100,000	118,833	218,833
2021	100,000	-	100,000
Total	$ 425,000	$434,876	$859,876

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BUSINESS

Our Business Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible florescent light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and 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).

Our Vaccines/BioDefense business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the 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 have advanced the development of OrbeShield® for the treatment of GI ARS with funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from the NIAID.

An outline of our business strategy follows:

- Complete enrollment and report preliminary results in our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL;
- Continue site initiation and enrollment of the pivotal Phase 3 trial of SGX942 for the treatment of oral mucositis in head and neck cancer patients;
- Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease contingent upon additional funding, such as through partnership and/or government funding support;

Continue development of RiVax® in combination with our ThermoVax® technology to develop new heat stable vaccines in biodefense with NIAID funding support;

Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS contingent upon government funding support;

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

Pursue business development opportunities for our pipeline programs, as well as explore merger/acquisition strategies; and

Acquire or in-license new clinical-stage compounds for development.

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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 compared to placebo; Phase 3 clinical trial initiated in December 2015, with data expected in the second half of 2018
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial completed; demonstrated significant response compared to placebo with positive long-term (12 month) safety also reported; Phase 3 clinical trial initiated July 2017, with data expected in the first half of 2019
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed; efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety profile demonstrated; Phase 3 clinical trial planned for the first half of 2018, with data expected in the second half of 2019
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial completed; safety profile and preliminary efficacy demonstrated

Vaccine Thermostability Platform**

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

BioDefense Products**

Soligenix Product Candidate	Indication	Stage of Development
RiVax®	Vaccine against Ricin Toxin Poisoning	Phase 1b trial complete, safety and neutralizing antibodies for protection demonstrated; Phase 1/2 trial planned for the first half of 2018
OrbeShield®	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943	Therapeutic against Infectious Diseases	Pre-clinical

*** Contingent upon continued government contract/grant funding or other funding source.*

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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 B-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

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 ($p \leq 0.04$) 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 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. SGX301 for the treatment of CTCL also was granted Orphan Drug designation from the European Medicines Agency ("EMA") Committee for Orphan Medical Products and Promising Innovative Medicine ("PIM") designation from the Medicines and Healthcare Products Regulatory Agency ("MHRA") in the United Kingdom ("UK").

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We initiated our pivotal Phase 3 clinical study of SGX301 for the treatment of CTCL during December 2015 and are actively enrolling patients. The Phase 3 protocol is expected to be a highly powered, double-blind, randomized, placebo-controlled, multicenter trial and will seek to enroll approximately 120 evaluable subjects. The trial will consist of three treatment cycles, each of eight weeks duration. Treatments will be administered twice weekly for the first six weeks and treatment response will be determined at the end of the eighth week. In the first treatment cycle, approximately 80 subjects will receive SGX301 and 40 will receive placebo treatment of their index lesions. In the second cycle, all subjects will receive SGX301 treatment of their index lesions, and in the third cycle all subjects will receive SGX301 treatment of all of their lesions. Subjects will be followed for an additional nine months after the completion of treatment. The primary efficacy endpoint will be assessed on the percentage of patients in each of the two treatment groups (i.e., SGX301 and placebo) achieving a partial or complete response of the treated lesions, defined as a ≥ 50% reduction in the total Composite Assessment of Index Lesion Disease Severity ("CAILS") score for three index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline. Other secondary measures will assess treatment response including duration, degree of improvement, time to relapse and safety.

During September 2017 we announced the National Cancer Institute ("NCI"), part of the National Institutes of Health ("NIH") awarded us a Small Business Innovation Research ("SBIR") grant of approximately $1.5 million over two years to support the conduct of our pivotal, Phase 3, randomized, double-blind, placebo-controlled study evaluating SGX301 (synthetic hypericin) as a treatment for CTCL.

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 and Industry Data and Market Information."

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.

Dusquetide

Dusquetide (research name: SGX94) is an innate defense regulator ("IDR") that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing.

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Dusquetide is based on a new class of short, synthetic peptides known as IDRs. It has a novel mechanism of action in that it modulates the body's reaction to both injury and infection and is both 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. Additionally, due to selective binding to p62, dusquetide may have potential anti-tumor action.

Dusquetide 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. Dusquetide was shown to have a good safety profile and be well-tolerated in all dose groups when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. Dusquetide is the subject of an open Investigational New Drug ("IND") application which has been cleared by the FDA. We believe that market opportunities for dusquetide include, but are not limited to, oral and gastrointestinal mucositis, acute Gram-positive bacterial infections (e.g., methicillin resistant *Staphylococcus aureus* (MRSA)), acute Gram-negative infections (e.g., acinetobacter, melioidosis), and acute radiation syndrome.

SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is our product candidate containing our IDR technology, dusquetide, 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 addition, dusquetide has been granted PIM designation in the UK by the MHRA for the treatment of severe oral mucositis in head and neck cancer patients receiving chemoradiation therapy.

We initiated a Phase 2 clinical study of SGX942 for the treatment of oral mucositis in head and neck cancer patients in December of 2013. We completed enrollment in this trial in the second half of 2015, and in December 2015 released positive preliminary results. In this Phase 2 proof-of-concept clinical study that enrolled 111 patients, SGX942, at a dose of 1.5 mg/kg, successfully reduced the median duration of severe oral mucositis by 50%, from 18 days to 9 days ($p=0.099$) in all patients and by 67%, from 30 days to 10 days ($p=0.040$) in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. The p-values met the prospectively defined statistical threshold of $p<0.1$ in the study protocol. In addition to identifying the best dose of 1.5 mg/kg, this study achieved all objectives, including increased incidence of "complete response" of tumor at the one month follow-up visit (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and decreases in infection rate were also

observed with SGX942 treatment, consistent with the preclinical results observed in animal models. SGX942 was found to be generally safe and well tolerated, consistent with the safety profile observed in the prior Phase 1 study conducted in 84 healthy volunteers. The long-term (12 month) follow-up data was consistent with the preliminary positive safety and efficacy findings. While the placebo population experienced the expected 12-month survival rate of approximately 80%, as defined in the Surveillance, Epidemiology, and End Results statistics 1975-2012 from the National Cancer Institute, the SGX942 1.5 mg/kg treatment group reported a 12-month survival rate of 93% (7% mortality in the SGX942 1.5 mg/kg group compared to 19% in the placebo group). Similarly, tumor resolution (complete response) at 12 months was better in the SGX942 1.5 mg/kg treatment group relative to the placebo population (80% in the 1.5 mg/kg group compared to 74% in the placebo group). The long-term follow-up results from the Phase 2 study are reviewed in "Dusquetide: Reduction in Oral Mucositis associated with Enduring Ancillary Benefits in Tumor Resolution and Decreased Mortality in Head and Neck Cancer Patients" published online in Biotechnology Reports and available at the following link: https://doi.org/10.1016/j.btre.2017.05.002. In addition to safety, evaluations of other secondary efficacy endpoints, such as the utilization of opioid pain medication, indicated that the SGX942 1.5mg/kg treatment group had a 40% decrease in the use of opioids at the later stage of the treatment phase of the trial, when oral mucositis is usually most severe and expected to increase paid medication use. This was in contrast to the placebo group, which demonstrated a 10% increase in use of opioids over this same period. Data from this Phase 2 trial was published online in the Journal of Biotechnology. The publication also delineates the supportive nonclinical data in this indication, demonstrating consistency in the qualitative and quantitative biological response, including dose response, across the nonclinical and clinical data sets. The results are available at the following link: http://authors.elservier.com/sd/article/S01681656116315668.