

SOLIGENIX, INC.  
Form 424B3  
November 30, 2017

**Filed Pursuant to Rule 424(b)(3)**

**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 fluorescent 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<sup>®</sup>, our ricin toxin vaccine candidate, OrbeShield<sup>®</sup>, 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<sup>®</sup>, 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<sup>®</sup> to protect against exposure to ricin toxin. We have advanced the development of OrbeShield<sup>®</sup> 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**

<b>Soligenix Product Candidate</b>	<b>Therapeutic Indication</b>	<b>Stage of Development</b>
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\*\***

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

**BioDefense Products\*\***

<b>Soligenix Product Candidate</b>	<b>Indication</b>	<b>Stage of Development</b>
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 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 expressions. These statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed for the reasons described in this prospectus. You should not place undue reliance on these forward-looking statements.

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

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

the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our proposed products, including: (i) the timing, status and results of our or our commercial partners’ filings with the U.S. Food and Drug Administration (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.

Period	Price Range	
	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	<b>Number of Securities to be Issued upon</b>	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	<b>Number of Securities Remaining Available for Future</b>
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	<b>Exercise of Outstanding Options, Warrants and Rights</b>		<b>Issuance Under Equity Compensation Plans  (excluding securities reflected in the first column)</b>
Equity compensation plans approved by security holders (1)	330,605	\$ 17.07	185,769
Equity compensation plans not approved by security holders	-	-	-
<b>Total</b>	<b>330,605</b>	<b>\$ 17.07</b>	<b>185,769</b>

(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<sup>®</sup>, our ricin toxin vaccine candidate, OrbeShield<sup>®</sup>, 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<sup>®</sup>, 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<sup>®</sup> to protect against exposure to ricin toxin. We have advanced the development of OrbeShield<sup>®</sup> 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 <sup>®</sup> and ThermoVax <sup>®</sup> 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 <sup>®</sup>	171,618	3,254,204

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RiVax <sup>®</sup> and ThermoVax <sup>®</sup> 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:

<b>Year</b>	Research and Development	<b>Property and Other Leases</b>		<b>Total</b>
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<sup>®</sup>, our ricin toxin vaccine candidate, OrbeShield<sup>®</sup>, 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<sup>®</sup>, 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<sup>®</sup> to protect against exposure to ricin toxin. We have advanced the development of OrbeShield<sup>®</sup> 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<sup>®</sup> in combination with our ThermoVax<sup>®</sup> technology to develop new heat stable vaccines in biodefense with NIAID funding support;

Advance the preclinical and manufacturing development of OrbeShield<sup>®</sup> 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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The following tables summarize our product candidates under development:

**BioTherapeutic Product Candidates**

<b>Soligenix Product Candidate</b>	<b>Therapeutic Indication</b>	<b>Stage of Development</b>
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\*\***

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

**BioDefense Products\*\***



<b>Soligenix Product Candidate</b>	<b>Indication</b>	<b>Stage of Development</b>
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  $\geq 50\%$  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 opioid 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.elsevier.com/sd/article/S01681656116315668>.

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On September 9, 2016, we and SciClone Pharmaceuticals, Inc. (“SciClone”) entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in defined territories. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in the territories, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

We have received clearance from the FDA to advance the pivotal Phase 3 protocol for SGX942 in the treatment of oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. Additionally, we have received positive Scientific Advice from the EMA for the development of SGX942 as a treatment for oral mucositis in patients with head and neck cancer. The Scientific Advice from the EMA indicates that a single, double-blind, placebo-controlled, multinational, Phase 3 pivotal study, if successful, in conjunction with the Phase 2 dose-ranging study, is generally considered sufficient to support a marketing authorization application (“MAA”) to the EMA for potential licensure in Europe. The advice also provided several suggestions to strengthen the study design and data collection that will be integrated into the final protocol. Scientific Advice is offered by the EMA to stakeholders for clarification of questions arising during development of medicinal products. The scope of Scientific Advice is limited to scientific issues and focuses on development strategies rather than pre-evaluation of data to support an MAA. Scientific Advice is legally non-binding and is based on the current scientific knowledge which may be subject to future changes.

We had been working with leading oncology centers, a number of which participated in the Phase 2 study, to advance this Phase 3 clinical trial referred to as the “DOM-INNATE” study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity). Based on the positive and previously published Phase 2 results (Study IDR-OM-01), the pivotal Phase 3 clinical trial (Study IDR-OM-02) will be a highly powered, double-blind, randomized, placebo-controlled, multinational trial that will seek to enroll approximately 190 subjects with squamous cell carcinoma of the oral cavity and oropharynx who are scheduled to receive a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m<sup>2</sup> every third week. Subjects will be randomized to receive either 1.5 mg/kg SGX942 or placebo given twice a week during and for two weeks following completion of chemoradiation therapy (“CRT”). The primary endpoint for the study will be the median duration of severe oral mucositis, which will be assessed by oral examination at each treatment visit and then through six weeks following completion of CRT. Oral mucositis will be evaluated using the WHO Grading system. Severe oral mucositis is defined as a WHO Grade of  $\geq 3$ . Subjects will be followed for an additional 12 months after the completion of treatment.

During July 2017, we initiated our pivotal Phase 3 study with a controlled roll-out of U.S. study sites, and will follow with the addition of European centers in 2018.

During September 2017, the National Institute of Dental and Craniofacial Research (“NIDCR”), part of the NIH, awarded us a SBIR grant of approximately \$1.5 million over two years to support the conduct of our Phase 3, multinational, randomized, double-blind, placebo-controlled study evaluating SGX942 (dusquetide) as a treatment for



severe oral mucositis in patients with head and neck cancer receiving CRT.

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

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### **Oral Mucositis**

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

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

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

### **Oral BDP**

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

Based on its pharmacological characteristics, oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We are planning to pursue development programs for the treatment of pediatric Crohn's disease, acute radiation enteritis and GI ARS pending further grant funding. We are also exploring the possibility of testing oral BDP for local inflammation associated with ulcerative colitis, among other indications.

We are pursuing Orphan Drug designations for relevant indications as appropriate in both the U.S. and Europe. An Orphan Drug designation provides for seven years of market exclusivity upon approval in the U.S. and Europe, respectively.

***SGX203 – for Treating Pediatric Crohn’s Disease***

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

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

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**Pediatric Crohn's Disease**

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

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

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

***SGX201 – for Preventing Acute Radiation Enteritis***

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. In 2012, we completed a Phase 1/2 clinical trial testing SGX201 in prevention of acute radiation enteritis. Patients with rectal cancer scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. The objectives of the study were to evaluate the safety and maximal tolerated dose of escalating doses of SGX201, as well as the preliminary efficacy of SGX201 for prevention of signs and symptoms of acute radiation enteritis. The study demonstrated that oral administration of SGX201 was safe and well tolerated across all four dose groups. There was also evidence of a potential dose response with respect to diarrhea, nausea and vomiting and the assessment of enteritis according to National Cancer Institute Common Terminology Criteria for Adverse Events for selected gastrointestinal events. In addition, the incidence of diarrhea was lower than that seen in recent published historical control data in this patient population. This program was supported in part by a \$500,000 two-year SBIR grant awarded by the NIH. We continue to work with our Radiation Enteritis medical advisors to identify additional funding opportunities to support the clinical development program.

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

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

### **Acute Radiation Enteritis**

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

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

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

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

## Vaccines/BioDefense Overview

### *ThermoVax<sup>®</sup> – Thermostability Technology*

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

ThermoVax<sup>®</sup> development was supported pursuant to our \$9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax<sup>®</sup>) and anthrax (VeloThrax<sup>®</sup>) vaccines. Proof-of-concept preclinical studies with

ThermoVax<sup>®</sup> indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with our aluminum-adjuvanted ricin toxin vaccine, RiVax<sup>®</sup> and our aluminum-adjuvanted anthrax vaccine, VeloThrax<sup>®</sup>. Each vaccine was manufactured under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the key antigen. When RiVax<sup>®</sup> was kept at 40 degrees C (104 degrees Fahrenheit) for up to one year, all of the animals vaccinated with the lyophilized RiVax<sup>®</sup> vaccine developed potent and high titer neutralizing antibodies. In contrast, animals that were vaccinated with the liquid RiVax<sup>®</sup> vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C. When VeloThrax<sup>®</sup> was kept for up to 16 weeks at 70 degrees C, it was able to develop a potent antibody response, unlike the liquid formulation kept at the same temperature. Moreover, we also have demonstrated the compatibility of our thermostabilization technology with other secondary adjuvants such as TLR-4 agonists. Additionally, the University of Colorado conducted a study that demonstrated a heat stable vaccine formulation of a human papillomavirus (“HPV”) vaccine. The work was conducted by Drs. Randolph and Garcea and demonstrated the successful conversion of a commercial virus-like-particle based vaccine requiring cold chain storage to a subunit, alum-adjuvanted, vaccine which is stable at ambient temperatures. This work, funded by a University of Colorado seed grant and the Specialized Program of Research Excellence in cervical cancer, is the first demonstration of the utility of ThermoVax<sup>®</sup> technology for the development of a subunit based commercial vaccine. The HPV vaccine formulation was found to be stable for at least 12 weeks at 50 degrees C. In the study, mice immunized with the ThermoVax<sup>®</sup>-stabilized HPV subunit vaccine were also found to achieve immune responses similar to the commercial HPV vaccine, Cervarix<sup>®</sup>, as measured by either total antibody levels or neutralizing antibody levels. Moreover, whereas the immune responses to Cervarix<sup>®</sup> were reduced after storage for 12 weeks at 50 degrees C, the ThermoVax<sup>®</sup> formulated vaccine retained its efficacy. The results were published online in the European Journal of Pharmaceutics and Biopharmaceutics. See <http://www.sciencedirect.com/science/article/pii/S0939641115002416>.

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We also entered into a collaboration agreement with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawai'i at Manoa ("UH Manoa") and Hawaii Biotech, Inc. ("HBI") to develop a heat stable subunit Ebola vaccine. Dr. Lehrer, a co-inventor of the Ebola vaccine with HBI, has shown proof of concept efficacy with subunit Ebola vaccines in non-human primates. The most advanced Ebola vaccines involve the use of vesicular stomatitis virus and adenovirus vectors – live, viral vectors which complicate the manufacturing, stability and storage requirements. Dr. Lehrer's vaccine candidate is based on highly purified recombinant protein antigens, circumventing many of these manufacturing difficulties. Dr. Lehrer and HBI have developed a robust manufacturing process for the required proteins. Application of ThermoVax® may allow for a product that can avoid the need for cold chain distribution and storage, yielding a vaccine ideal for use in both the developed and developing world. Although this agreement has expired in accordance with its terms, we expect to extend the period of the agreement or enter into another agreement with Dr. Lehrer and HBI to replace this agreement.

During September 2017 we announced we will be participating in a Research Project (R01) grant awarded to UH Manoa for the development of a thermostabilized Ebola vaccine, with our awarded funding of approximately \$700,000 over 5 years. Previous collaborations demonstrated the feasibility of developing a heat stable subunit Ebola vaccine. Under the terms of the subaward, we will continue to support vaccine formulation development with our proprietary vaccine thermostabilization technology, ThermoVax®. Ultimately, the objective is to produce a thermostable trivalent filovirus vaccine for protection against Ebola and related diseases, allowing worldwide distribution without the need for cold storage.

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

### ***RiVax™ – Ricin Toxin Vaccine***

RiVax® is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin and if approved, would be the first ricin vaccine. The immunogen in RiVax® induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated ricin A chain subunit that is enzymatically inactive and lacks residual toxicity of the holotoxin. RiVax® has demonstrated statistically significant ( $p < 0.0001$ ) preclinical survival results, providing 100% protection against acute lethality in an aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, PNAS USA 112:3782-3787), and has also been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Results of the first Phase 1 human trial of RiVax® established that the immunogen was safe and induced antibodies that we believe may protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating



that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial which was completed in September 2012 and was sponsored by University of Texas Southwestern Medical Center (“UTSW”), evaluated a more potent formulation of RiVax<sup>®</sup> that contained an aluminum adjuvant (Alum). The results of the Phase 1b study indicated that Alum-adjuvanted RiVax<sup>®</sup> was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax<sup>®</sup>. The outcomes of this second study were published in the Clinical and Vaccine Immunology (Vitetta et al., 2012, Recombinant Ricin Vaccine Phase 1b Clinical Trial, Clin. Vaccine Immunol. 10:1697-1699). We have adapted the original manufacturing process for the immunogen contained in RiVax<sup>®</sup> for thermostability and large scale manufacturing and recent studies have confirmed that the thermostabilized RiVax<sup>®</sup> formulation significantly enhances the stability of the RiVax<sup>®</sup> antigen, enabling storage for at least 1 year at temperatures up to 40°C (104 °F). The program will pursue approval via the FDA “Animal Rule” since it is not possible to test the efficacy of the vaccine in a clinical study which would expose humans to ricin. Uniform, easily measured and species-neutral immune correlates of protection that can be measured in humans and animals, and are indicative of animal survival to subsequent ricin challenge, are central to the application of the “Animal Rule”. Recent work has identified such potential correlates of immune protection in animals and work to qualify and validate these approaches is continuing, with the goal of utilizing these assays in a planned Phase 1/2 clinical trial with the thermostable RiVax<sup>®</sup> formulation. We have entered into a collaboration with IDT Biologika GmbH to scale-up the formulation/filling process and continue development and validation of analytical methods established at IDT to advance the program. We also have initiated a development agreement with Emergent BioSolutions, Inc. to implement a commercially viable, scalable production technology for the RiVax<sup>®</sup> drug substance protein antigen.

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The development of RiVax<sup>®</sup> has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to Soligenix and to UTSW where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. To date, we and UTSW have collectively received approximately \$25 million in grant funding from the NIH for the development of RiVax<sup>®</sup>. In September 2014, we entered into a contract with the NIH for the development of RiVax<sup>®</sup> that would provide up to an additional \$24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH. The development agreements with Emergent BioSolutions and IDT are specifically funded under this NIH contract.

During June 2017 NIAID exercised an option for the evaluation of RiVax<sup>®</sup> to fund additional animal efficacy studies. The exercised option will provide us with approximately \$2.0 million in additional funding. Additionally, during August 2017 NIAID exercised an option to fund GMP (good manufacturing practices) compliant RiVax<sup>®</sup> bulk drug substance and finished drug product manufacturing, which is required for the conduct of future preclinical and clinical safety and efficacy studies. The exercised option will provide us with approximately \$2.5 million in additional non-dilutive funding, bringing the total amount awarded to date under this contract to \$21.2 million, of which \$17.9 million is still available. If all contract options are exercised, the total award of up to \$24.7 million will support the preclinical, manufacturing and clinical development activities necessary to advance heat stable RiVax<sup>®</sup> with the U.S. FDA.

RiVax<sup>®</sup> has been granted Orphan Drug designation by the FDA for the prevention of ricin intoxication.

Assuming development efforts are successful for RiVax<sup>®</sup>, we believe potential government procurement contract(s) could reach \$200 million. This potential procurement contract information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential procurement contract value based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements and Industry Data and Market Information."

As a new chemical entity, an FDA approved RiVax<sup>®</sup> vaccine has the potential to qualify for a biodefense Priority Review Voucher ("PRV"). Approved under the 21st Century Cures Act in late 2016, the biodefense PRV is awarded upon approval as a medical countermeasure when the active ingredient(s) have not been otherwise approved for use in any context. PRVs are transferable and can be sold, with sales in recent years varying from between \$125 million to \$350 million. When redeemed, PRVs entitle the user to an accelerated review period of nine months, saving a median of seven months review time as calculated in 2009. However, FDA must be advised 90 days in advance of the use of the PRV and the use of a PRV is associated with an additional user fee (\$2.7 million in 2017).

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### **Ricin Toxin**

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

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

### ***OrbeShield® –for Treating GI Acute Radiation Syndrome***

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

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

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology,

where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. We are seeking to treat the same type of toxicity in our acute radiation enteritis clinical program with SGX201. As a result, we believe that OrbeShield® has the potential to be a “dual use” compound, a desirable characteristic which is a specific priority for ARS and other medical countermeasure indications. The FDA has cleared the IND application for OrbeShield® for the mitigation of morbidity and mortality associated with GI ARS.

In September 2013, we received two government contracts from BARDA and NIAID for the advanced preclinical and manufacturing development of OrbeShield® leading to FDA approval to treat GI ARS. The BARDA contract contained a two year base period with two contract options, exercisable by BARDA, for a total of five years and up to \$26.3 million. The NIAID contract consisted of a one year base period and two contract options, exercisable by NIAID, for a total of three years and up to \$6.4 million. We received a combined approximate \$18 million in contract funding from both BARDA and NIAID which includes combined supplemental funding of \$634,000, extending the programs through the first quarter of 2017. The NIAID contract was completed 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. We will continue to apply for additional government funding. Previously, development of OrbeShield® had been largely supported by a \$1 million NIH grant to our academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, we received an SBIR grant from NIAID of approximately \$600,000 to support further preclinical development of OrbeShield® for the treatment of acute GI ARS. The FDA has given OrbeShield® Orphan Drug designation and Fast Track designation for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

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

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**GI Acute Radiation Syndrome**

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

***SGX943 – for Treating Emerging and/or Antibiotic-Resistant Infectious Diseases***

SGX943 is an IDR, containing the same active ingredient as SGX942. Dusquetide is a fully synthetic, 5-amino acid peptide with high aqueous solubility and stability. Extensive *in vivo* preclinical studies have demonstrated enhanced clearance of bacterial infection with SGX943 administration. SGX943 has shown efficacy against both gram-negative and gram-positive bacterial infections in preclinical models, independent of whether the bacteria is antibiotic-resistant or antibiotic-sensitive.

The innate immune system is responsible for rapid and non-specific responses to combat bacterial infection. Augmenting these responses represents an alternative approach to treating bacterial infections. In animal models, IDRs are efficacious against both antibiotic-sensitive and antibiotic-resistant infections, both gram-positive and gram-negative bacteria, and are active irrespective of whether the bacteria occupies a primarily extracellular or intracellular niche. IDRs are also effective as stand-alone agents or in conjunction with antibiotics. An IDR for the treatment of serious bacterial infections encompasses a number of clinical advantages including:

Treatment when antibiotics are contraindicated, such as:

- o before the infectious organism and/or its antibiotic susceptibility is known; or
- o in at-risk populations prior to infection.

An ability to be used as an additive, complementary treatment with antibiotics, thereby:

o enhancing efficacy of sub-optimal antibiotic regimens (e.g., partially antibiotic-resistant infections);

o enhancing clearance of infection, thereby minimizing the generation of antibiotic resistance (e.g., in treating melioidosis); and

o reducing the required antibiotic dose, again potentially minimizing the generation of antibiotic resistance.

An ability to modulate the deleterious consequences of inflammation in response to the infection, including the inflammation caused by antibiotic-driven bacterial lysis; and

Being unlikely to generate bacterial resistance since the IDR acts on the host, and not the pathogen.

Importantly, systemic inflammation and multi-organ failure is the ultimate common outcome of not only emerging and/or antibiotic-resistant infectious diseases, but also of most biothreat agents (e.g., *Burkholderia pseudomallei*), indicating that dusquetide would be applicable not only to antibiotic-resistant infection, but also to biothreat agents, especially where the pathogen is not known and/or has been engineered for enhanced antibiotic resistance.

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**The Drug Approval Process**

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements on the clinical development, manufacture and marketing of new drug and biologic products. The FDA, through regulations that implement the Federal Food, Drug, and Cosmetic Act, as amended (“FDCA”), and other laws and comparable regulations for other agencies, regulate research and development activities and the testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale, export, import and distribution of such products. The regulatory approval process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including holds on clinical research, civil or criminal fines or other penalties, product recalls, or seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

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

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

With certain exceptions, once successful clinical testing is completed, the sponsor can submit a New Drug Application (“NDA”), for approval of a drug, or a Biologic License Application (“BLA”), for biologics such as vaccines, which will be reviewed, and if successful, approved by the FDA, allowing the product to be marketed. The process of completing clinical trials for a new drug is likely to take a number of years and require the expenditure of substantial resources. Furthermore, the FDA or any foreign health authority may not grant an approval on a timely basis, if at all. The FDA may deny the approval of an NDA or BLA, in its sole discretion, if it determines that its regulatory criteria have not been satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer’s quality control and manufacturing procedures conform to good manufacturing practice regulations. In complying with standards contained in these regulations, manufacturers must continue to expend time, money and effort in the area of production, quality control and quality assurance to ensure full technical compliance. Manufacturing facilities, both foreign and domestic, also are subject to inspections by, or

under the authority of, the FDA and by other federal, state, local or foreign agencies.

Even after initial FDA or foreign health authority approval has been obtained, further studies, including Phase 4 post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the marketing of a product as a treatment for clinical indications other than those for which the product was initially tested. For certain drugs intended to treat serious, life-threatening conditions that show great promise in earlier testing, the FDA can also grant conditional approval. However, drug developers are required to study the drug further and verify clinical benefit as part of the conditional approval provision, and the FDA can revoke approval if later testing does not reproduce previous findings. The FDA may also condition approval of a product on the sponsor agreeing to certain mitigation strategies that can limit the unfettered marketing of a drug. Also, the FDA or foreign regulatory authority will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the product. Further, if there are any modifications to the drug, including any change in indication, manufacturing process, labeling or manufacturing facility, an application seeking approval of such changes will likely be required to be submitted to the FDA or foreign regulatory authority.



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

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

Vaccines are approved under the BLA process that exists under the Public Health Service Act. In addition to the greater technical challenges associated with developing biologics, the potential for generic competition is lower for a BLA product than a small molecule product subject to an NDA under the Federal Food, Drug and Cosmetic Act. Under the Patient Protection and Affordable Care Act enacted in 2010, a “generic” version of a biologic is known as a biosimilar and the barriers to entry – whether legal, scientific, or logistical – for a biosimilar version of a biologic approved under a BLA are higher.

### ***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a

particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

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***Fast Track Designation and Accelerated Approval***

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

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

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

***Pediatric Information***

Under the Pediatric Research Equity Act ("PREA"), NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe

and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

### *Early Access to Medicines Scheme*

Launched in April 2014 in the United Kingdom by the MHRA, the Early Access to Medicines Scheme (“EAMS”) offers severely ill patients with life-threatening and seriously debilitating conditions the lifeline of trying ground-breaking new medicines earlier than they would normally be accessible. PIM designation is the first phase of EAMS and is awarded following an assessment of early nonclinical and clinical data by the MHRA. The criteria product candidates must meet to obtain PIM designation are:

Criterion 1 – The condition should be life-threatening or seriously debilitating with a high unmet medical need (i.e., there is no method of treatment, diagnosis or prevention available or existing methods have serious limitations).

Criterion 2 – The medicinal product is likely to offer major advantage over methods currently used in the UK.

Criterion 3 – The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance. A positive benefit risk balance should be based on preliminary scientific evidence that the safety profile of the medicinal product is likely to be manageable and acceptable in relation to the estimated benefits.

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***False Claims Laws***

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

***Anti-Kickback Laws***

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

***United States Healthcare Reform***

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

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to “business associates” – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages

or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

### **Third-Party Suppliers and Manufacturers**

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

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

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### **Marketing and Collaboration**

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

authorities of the U.S. and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.



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

On August 25, 2013, we entered into an agreement with SciClone Pharmaceuticals, Inc. (“SciClone”), pursuant to which SciClone provided us with access to its oral mucositis clinical and regulatory data library in exchange for exclusive commercialization rights for SGX942 in the People’s Republic of China, including Hong Kong and Macau, subject to the negotiation of economic terms. SciClone’s data library was generated from two sequential Phase 2 clinical studies conducted in 2010 and 2012 evaluating SciClone’s compound, SCV-07, for the treatment of oral mucositis caused by chemoradiation therapy in head and neck cancer patients, before SciClone terminated its program. By analyzing data available from the placebo subjects in the SciClone trials, we acquired valuable insight into disease progression, along with quantitative understanding of its incidence and severity in the head and neck cancer patient population. This information assisted us with the design of the SGX942 Phase 2 clinical trial, in which positive preliminary results were announced in December 2015.

On September 9, 2016, we and SciClone entered into an exclusive license agreement, pursuant to which we granted rights to SciClone to develop, promote, market, distribute and sell SGX942 in the People’s Republic of China, including Hong Kong and Macau, as well as Taiwan, South Korea and Vietnam. Under the terms of the license agreement, SciClone will be responsible for all aspects of development, product registration and commercialization in the territory, having access to data generated by us. In exchange for exclusive rights, SciClone will pay us royalties on net sales, and we will supply commercial drug product to SciClone on a cost-plus basis, while maintaining worldwide manufacturing rights.

We also entered into a common stock purchase agreement with SciClone pursuant to which we sold 352,942 shares of our common stock to SciClone for approximately \$8.50 per share, for an aggregate price of \$3,000,000. As part of the transaction, we granted SciClone certain demand registration rights, and SciClone agreed, subject to certain exceptions, not to pledge, sell or otherwise transfer or dispose of, or enter into any swap or other arrangement that transfers any of the economic consequences of ownership of, the shares purchased for at least one year from September 9, 2016.

## **Competition**

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

### ***SGX301 Competition***

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

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***SGX94/942 Competition***

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

There is currently one drug approved for the treatment of oral mucositis in hematological cancer (palifermin). There are currently no approved drugs for treatment of oral mucositis in cancers with solid tumors (e.g., head and neck cancer). There are several drugs in clinical development for oral mucositis – one in Phase 3 (under development by Daewoong Pharmaceutical Co., Ltd.), four in Phase 2 (under development by Cellceutix Corporation, BioAlliance Pharma S.A., Onexeo S.A., and Alder Biopharmaceuticals Inc.) and one in Phase 1 (under development by ActoGenix N.V.). In addition, there are medical devices approved for the treatment of oral mucositis including MuGard, GelClair, Episil and Caphosol. These devices attempt to create a protective barrier around the oral ulceration with no biologic activity in treating the underlying disease.

***Oral BDP Competition***

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

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

***ThermoVax® Competition***

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

Several stabilization technologies currently being developed involve mixing vaccine antigen +/- adjuvant with various proprietary excipients or co-factors that either serve to stabilize the vaccine or biological product in a liquid or dried (lyophilized) form. Examples of these approaches include the use of various plant-derived sugars and macromolecules being developed by companies such as Stabilitech Ltd. Variation Biotechnologies, Inc. ("VBI") is developing a lipid system (resembling liposomes) to stabilize viral antigens, including virus-like particles (VLPs), and for potential application to a conventional influenza vaccine among others.

Other approaches involve process variations to freeze-dry live virus vaccines. For example, PaxVax, Inc. is seeking to employ a spray drying technology in concert with enteric coating to achieve formulations for room temperature stability of live virus vaccines using adenovirus vectors. VBI is seeking to utilize their proprietary stabilization technology for a number of vaccines (as a co-development service, similar to the business model being developed by Stabilitech Ltd.), whereas PaxVax is applying the technology to their own proprietary vaccine development programs. Stabilitech uses combinations of excipients, which include glassifying sugars similar to the ThermoVax<sup>®</sup> technology, and variations in drying cycles during lyophilization, as does the ThermoVax<sup>®</sup> technology.

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

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***Vaccines/BioDefense Competition***

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

The U.S. Army Medical Research Institute of Infectious Diseases, the DoD's lead laboratory for medical research to counter biological threats is also developing a ricin vaccine candidate, RVEc™. RVEc™ has been shown to be fully protective in mice exposed to lethal doses of ricin toxin by the aerosol route. Further studies, in both rabbits and nonhuman primates, were conducted to evaluate RVEc™'s safety as well as its immunogenicity, with positive results observed.

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

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

**Patents and Other Proprietary Rights**

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

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

In 2014, we acquired a novel photodynamic therapy that utilizes safe visible light for activation, which we refer to as SGX301. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. As part of the acquisition, we acquired a license agreement relating to the use of photo-activated hypericin, composition of matter patent for SGX301 (U.S. patent 8,629,302) and additional issued and pending applications, both in the US and abroad. U.S. patent 8,629,302 is expected to expire in June 2032. Our proprietary formulation of synthetic hypericin has been granted a European patent for the treatment of psoriasis, EP 2571507, and complements the method of treatment claims covered by the previously issued US patent 6001882, Photoactivated hypericin and the use thereof.

In addition to issued and pending patents, we also have “Orphan Drug” designations for SGX301 in the U.S. and the EU for CTCL, SGX203 in the U.S. for pediatric Crohn’s disease, and OrbeShield® in the U.S. for GI ARS, as well as for RiVax™ in the U.S. Our Orphan Drug designations provide for seven years of post-approval marketing exclusivity in the U.S. and ten years exclusivity in Europe. We have pending patent applications for this indication that, if granted, may extend our anticipated marketing exclusivity beyond the U.S. seven year or E.U. ten year post-approval exclusivity provided by Orphan Drug legislation.

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In 2013, we expanded our patent portfolio to include innate defense regulation through the acquisition of the novel drug technology, known as SGX94. By binding to the pivotal regulatory protein p62, also known as sequestosome-1, SGX94 regulates the innate immune system to reduce inflammation, eliminate infection and enhance healing. As part of the acquisition, we acquired all rights, including composition of matter patents for SGX94 as well as other analogs and crystal structures of SGX94 with its protein target p62, including U.S. patent 8,124,721 and additional pending applications, both in the US and abroad. SGX94 was developed pursuant to discoveries made by Professors B. Brett Finlay and Robert Hancock of University of British Columbia (“UBC”). U.S. patent 8,124,721 is expected to expire in April 2028.

We have issued U.S. patents 8,263,582 and 6,096,731 that cover the use of oral BDP for treating inflammatory disorders of the gastrointestinal tract and the prevention and treatment of GI GVHD, respectively. U.S. patent numbers 8,263,582 and 6,096,731 are expected to expire in March 2022 and June 2018, respectively. We also have European patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract, as well as European patent EP 2242477 claiming the use of orally ingested BDP for treatment of interstitial lung disease. European patents EP 1392321 and EP 2242477 are expected to expire in March 2022 and January 2029.

The subject of U.S. patent application number 12/633,631 filed December 8, 2009 and corresponding European patent application number 09836727.9 is the use of topically active BDP in radiation and chemotherapeutics injury. Additionally, we have numerous patent filings currently issued or pending in foreign jurisdictions covering this subject matter, including Australia, Canada, China, Hong Kong, Israel, India, Japan, South Korea and New Zealand.

ThermoVax<sup>®</sup> is the subject of U.S. patent 8,444,991 issued on May 21, 2013 titled “Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition” and also U.S. patent application number 13/474,661 filed May 17, 2012 titled “Thermostable Vaccine Compositions and Methods of Preparing Same.” The patent application and the corresponding foreign filings for both patents are pending and licensed to us by the University of Colorado (“UC”) and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers thermostable vaccines for biodefense as well as other potential vaccine indications. U.S. patent 8,444,991 is expected to expire in December 2031.

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

***SGX301 License Agreement***

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

We acquired the license agreement for SGX301 and related intangible assets, including U.S. patent 8,629,302, properties and rights pursuant to an asset purchase agreement with Hy Biopharma Inc. (“Hy Biopharma”). As consideration for the assets acquired, we paid \$275,000 in cash and issued 184,912 shares of common stock with a market value of \$3,750,000. Provided all future success-orientated milestones are attained, we will be required to make payments of up to \$10.0 million, if and when achieved, payable in common stock of the Company.



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***SGX94 License Agreements***

On December 18, 2012, we announced the acquisition of a first in class drug technology, known as SGX94 (dusquetide), representing a novel approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to reduce inflammation, eliminate infection and enhance tissue healing by binding to the pivotal regulatory protein p62, also known as sequestosome-1. As part of the acquisition, we acquired all rights, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94. We also assumed a license agreement with UBC to advance the research and development of the SGX94 technology. The license agreement with UBC provides us with exclusive worldwide rights to manufacture, distribute, market sell and/or license or sublicense products derived or developed from this technology. Under the license agreement we are obligated to pay UBC (i) an annual license maintenance fee of CAN \$1,000, and (ii) milestone payments which could reach up to CAN \$1.2 million. This license agreement (a) will automatically terminate if we file, or become subject to an involuntary filing, for bankruptcy, and (b) may be terminated by UBC in the event of, among other things, our insolvency, dissolution, grant of a security interest in the technology licensed to us pursuant to the license agreement, or material breach of or failure to perform material obligations under the license agreement or other research agreements between us and UBC.

***Oral BDP License Agreement***

On November 24, 1998, the Company, known at the time as Enteron Pharmaceuticals, Inc. (“Enteron”) and George B. McDonald (“Dr. McDonald”) entered into an exclusive license agreement for the rights to intellectual property, including know-how, relating to oral BDP. The Company has an exclusive license to commercially exploit the covered products worldwide, subject to Dr. McDonald’s right to make and use the technology for research purposes and the U.S. Government’s right to use the technology for government purposes. Pursuant to the license agreement, as amended, the Company is required to (i) reimburse Dr. McDonald for certain out-of-pocket expenses incurred by Dr. McDonald in connection with the patent applications and issued patents, (ii) pay Dr. McDonald \$300,000 upon approval by the FDA of the Company’s first NDA incorporating oral BDP; (iii) pay Dr. McDonald royalty payments equal to 3% of net sales of the covered products and (iv) pay Dr. McDonald \$400,000 in cash upon an approval of oral BDP by the European Medicines Agency.

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

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

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

### ***ThermoVax® License Agreement***

On December 21, 2010, we executed a worldwide exclusive license agreement with the UC for ThermoVax®, which is the subject of U.S. patent number 8,444,991 issued on May 21, 2013 titled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition." This patent and its corresponding foreign filings are licensed to us by the UC and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. U.S. Patent 8,444,991 is expected to expire in December 2031. The license agreement also covers thermostable vaccines for biodefense as well as other potential vaccine indications. In addition, we, in conjunction with UC, filed domestic and foreign patent applications claiming priority back to a provisional application filed on May 17, 2011 titled: "Thermostable Vaccine Compositions and Methods of Preparing Same." To maintain this license we are obligated to pay minimum annual license fees of \$15,000 until the initiation of clinical trials, \$20,000 following the initiation of a Phase 1 clinical trial, and \$50,000 following the first commercial sale of a product incorporating ThermoVax®. Under the license agreement we are obligated to pay the UC (i) royalty payments equal to 2% of net sales of the covered products, (ii) 15% of all income from sublicenses and (iii) milestone payments which could reach up to \$1.25 million.

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### ***RiVax™ License Agreement***

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

### **Research and Development Expenditure**

We spent approximately \$3.6 million and \$3.4 million in the nine months ended September 30, 2017 and 2016, respectively, and \$4.3 million and \$5.4 million in the years ended December 31, 2016 and 2015, respectively, on research and development. The amounts we spent on research and development per product during the nine months ended September 30, 2017 and 2016 and the years ended December 31, 2016, and 2015 are set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” beginning on page 26 on this prospectus.

### **Employees**

As of September 30, 2017, we had 19 full-time employees, eight of whom are MDs/PhDs.

### **Properties**

We currently lease approximately 6,200 square feet of office space at 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540. This office space currently serves as our corporate headquarters. In December 2014, the Company 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 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. Our office space is sufficient to satisfy our current needs.

## **Legal Proceedings**

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

Table of Contents**MANAGEMENT**

The table below contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of November 15, 2017:

Name	Age	Position
Christopher J. Schaber, PhD	51	Chairman of the Board, Chief Executive Officer and President
Keith L. Brownlie, CPA	65	Director
Marco M. Brughera, DVM	62	Director
Gregg A. Lapointe, CPA	59	Director
Robert J. Rubin, MD	71	Director
Jerome B. Zeldis, MD, PhD	67	Director
Oreola Donini, PhD	45	Chief Scientific Officer and Senior Vice President
Karen Krumeich	64	Chief Financial Officer, Senior Vice President and Corporate Secretary
Richard Straube, MD	66	Chief Medical Officer and Senior Vice President

**Christopher J. Schaber, PhD** has over 27 years of experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been our President and Chief Executive Officer and a director since August 2006. He was appointed Chairman of the Board on October 8, 2009. He also serves on the Board of Directors of the Biotechnology Council of New Jersey (“BioNJ”) since January 2009 and the Alliance for Biosecurity since October 2014, and has been a member of the corporate councils of both the National Organization for Rare Diseases (“NORD”) and the American Society for Blood and Marrow Transplantation (“ASBMT”) since October 2009 and July 2009, respectively. Prior to joining Soligenix, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, pre-clinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his BA degree from Western Maryland College, his MS degree in Pharmaceutics from Temple University School of Pharmacy and his PhD degree in Pharmaceutical Sciences from the Union Graduate School. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as an executive senior officer with our Company and Discovery Laboratories, Inc., and as a member of the Board of Directors of BioNJ; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

**Keith L. Brownlie, CPA** has been a director since June 2011. Mr. Brownlie currently serves on the Board of Directors of Celldex Therapeutics, Inc., a publicly traded biotechnology company that is developing targeted therapeutics to address devastating diseases. He also serves on the Board of Directors of Rxi Pharmaceuticals

Corporation, a publicly traded biotechnology company involved in the research and development of RNAi products for the diagnosis, prevention and treatment of human diseases, a position he has held since June 2012. From July 2013 until December 2014, Mr. Brownlie served on the Board of Directors of Cancer Genetics, Inc., a publicly traded, early stage diagnostics company. Mr. Brownlie served as a member of the Board of Directors of Epicept Corporation, a publicly traded, specialty pharmaceutical company focused on the clinical development and commercialization of pharmaceutical products for the treatment of cancer and pain, from April 2011 to August 2013 when Epicept Corporation merged with Immune Pharmaceuticals, Inc. From 1974 to 2010, Mr. Brownlie worked with the accounting firm of Ernst & Young LLP where he served as audit partner for numerous public companies and was the Life Sciences Industry Leader for the New York metro area. Mr. Brownlie received a BS in Accounting from Lehigh University and is a Certified Public Accountant in the state of New Jersey. Mr. Brownlie co-founded the New Jersey Entrepreneur of the Year Program and was Vice President and Trustee of the New Jersey Society of CPAs. In addition, he served as accounting advisor to the Board of the Biotechnology Council of New Jersey. Mr. Brownlie was selected to serve as a member of our Board of Directors because of his vast experience as an audit partner for numerous public companies and as a director of publicly traded specialty pharmaceutical and biotechnology companies.

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**Marco M. Brughera, DVM** joined the Board of Directors in October 2013. He is the Global Head Rare Disease of the Lediant Group, a position he has held since October 2012. Dr. Brughera serves as CEO on the Board of Directors of Lediant Biosciences SpA and as director on the Board of Directors of Lediant Biosciences Ltd, Lediant Biosciences, Inc., Fennec Pharmaceuticals, Inc. and Lee's Pharmaceutical Holdings Ltd. From December 2011 through January 2014, Dr. Brughera served on the Board of Directors of Gentium S.p.A., a publicly traded biopharmaceutical company. From January 2011 through October 2012, Dr. Brughera held several other positions with the Sigma-Tau Group, including Corporate Research and Development Managing Director of Sigma-Tau Industrie Farmaceutiche Riuntite S.p.A., President of Sigma-Tau Research Switzerland S.A. and board member of Sigma-Tau Pharmaceuticals, Inc. (now known as Lediant Biosciences, Inc.), and of Sigma-Tau Rare Diseases S.A. and Sigma-Tau Pharma Ltd. From 2004 to 2010, Dr. Brughera served as the Vice President of Preclinical Development at Nerviano Medical Sciences S.r.l. ("NMS Group"), a pharmaceutical oncology-focused integrated discovery and development company. He also served as the Managing Director at Accelera, S.r.l., an independent contract research organization affiliated with the NMS Group. From 1999 to 2004, Dr. Brughera held several senior level positions in the areas of discovery and development toxicology with Pharmacia Corporation and Pfizer, Inc. Prior to 1999, he held various positions at Pharmacia & Upjohn Company, Inc., and Farmitalia Carlo Erba S.p.A., an Italian pharmaceutical company. Dr. Brughera earned his degree in veterinary medicine from the University of Milan and is a European Registered Toxicologist. Dr. Brughera was selected to serve as a member our Board of Directors because of his background in the areas of drug discovery and development and his experience as an executive officer and a director in the pharmaceutical industry.

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

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

consulting company. From 1984 to 1987, Dr. Rubin served as a principal of ICF, Inc., a health care consulting company. From 1981 to 1984, Dr. Rubin served as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services and as an Assistant Surgeon General in the United States Public Health Service. Dr. Rubin has served on the Board of BioTelemetry, Inc. (formerly known as CardioNet, Inc.) since 2007. He is a board certified nephrologist and internist. Dr. Rubin received an undergraduate degree in Political Science from Williams College and his medical degree from Cornell University Medical College. Dr. Rubin was selected to serve as a member of our Board of Directors because of his vast experience in the health care industry, including his experience as a nephrologist, internist, clinical professor of medicine and Assistant Surgeon General, and his business experience in the pharmaceutical industry.



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**Jerome B. Zeldis, MD, PhD** has been a director since June 2011. Dr. Zeldis is currently Chief Medical Officer and President of Clinical Research, Drug Safety and Regulatory of Sorrento Therapeutics, Inc. He is also Executive Chair of Immodulon Therapeutics Ltd. and Chief Medical Officer and Principle at Celularity, Inc. Previously, Dr. Zeldis was Chief Executive Officer of Celgene Global Health and Chief Medical Officer of Celgene Corporation, a publicly traded, fully integrated biopharmaceutical company. He was employed by Celgene from 1997 to 2016. From September 1994 to February 1997, Dr. Zeldis worked at Sandoz Research Institute and the Janssen Research Institute in both clinical research and medical development. He has been a board member of several biotechnology companies and is currently on the boards of Metastat, Inc., PTC Therapeutics Inc., BioSig Technologies, Inc., the Castleman's Disease Organization and Alliqua, Inc. He has previously served on the boards of the NJ Chapter of the Arthritis Foundation and PTC Therapeutics, Inc. Additionally, he has served as Assistant Professor of Medicine at the Harvard Medical School (from July 1987 to September 1988), Associate Professor of Medicine at University of California, Davis from (September 1988 to September 1994), Clinical Associate Professor of Medicine at Cornell Medical School (January 1995 to December 2003) and Professor of Clinical Medicine at the Robert Wood Johnson Medical School (July 1998 to June 2010). Dr. Zeldis received a BA and an MS from Brown University, and an MD, and a PhD in Molecular Biophysics and Biochemistry from Yale University. Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and in Gastroenterology at the Massachusetts General Hospital and Harvard Medical School. Dr. Zeldis was selected to serve as a member of our Board of Directors because of his experience as an executive officer of a publicly traded biopharmaceutical company and in clinical research and medical development, and his experience in the health care industry, including his experience as an internist, gastroenterologist and professor of medicine.

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

**Karen Krumeich** has been with our company since June 2016 and is currently our Senior Vice President and Chief Financial Officer. Ms. Krumeich has served as Chief Financial Officer and Vice President of Finance for public and

private emerging-growth, start-up and national companies in various sectors of healthcare, including pharmaceuticals, medical devices and healthcare service companies. She has expertise in equity financings, both private and public, Sarbanes-Oxley compliance, acquisitions and integrations, strategic business development and operations analysis. Most recently Ms. Krumeich was the Vice President of Finance for Cerecor Inc., a clinical stage neuroscience company. At Cerecor she was involved in the company's equity financings and was responsible for all finance and administrative functions. Prior to joining Cerecor she was a CFO Partner with Tatum, LLC, a national consulting firm, and a member of the firm's National Healthcare Group. As a Partner with Tatum, she served as Interim Chief Financial Officer for drug development and medical device companies. Prior to joining Tatum in 2006, she was the Vice President of Finance and Chief Financial Officer of Strata Skin Sciences, Inc. (formerly Mela Sciences, Inc.), a publicly traded development-stage medical device company. At Mela Sciences, she played a key role in the company's initial public offering and was responsible for all functional areas of finance and accounting, administration, and investor relations. As Vice President of Finance of Gran Care Pharmacy, Inc., she was responsible for the financial leadership of the pharmacy division and directed an aggressive acquisition program. Ms. Krumeich began her career with a B.S. in Pharmacy from the University of Toledo, subsequently completed an accounting major and transitioned into finance after completing the CPA exam.

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

## **Board Leadership Structure**

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

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

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

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**Role of the Board of Directors in Risk Oversight**

One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, but rather administers this oversight function directly through the Board of Directors as a whole, as well as through various standing committees of our Board of Directors that address risks inherent in their respective areas of oversight. In particular, our Board of Directors is responsible for monitoring and assessing strategic risk exposure and our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements. Our Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

**Director Independence**

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

**Committees of the Board of Directors**

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

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

– Committee Chair

– Member

*Audit Committee*

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

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*Compensation Committee*

Our Board of Directors has a Compensation Committee, which is comprised of Dr. Rubin (Chair), Dr. Brughera and Dr. Zeldis. The Compensation Committee is responsible for reviewing and approving the executive compensation program, assessing executive performance, setting salary, making grants of annual incentive compensation and approving certain employment agreements. Our Board of Directors has determined that Dr. Brughera, Dr. Rubin, and Dr. Zeldis are “independent” directors within the meaning of applicable listing standards of Nasdaq and the Exchange Act and the rules and regulations thereunder.

*Nominating and Corporate Governance Committee*

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

**Code of Ethics**

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

**Diversity Considerations in Identifying Director Nominees**

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

### **Compensation Committee Interlocks and Insider Participation**

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

### **Stock Ownership Policy**

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

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



Table of Contents**EXECUTIVE COMPENSATION****Summary Compensation**

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2016 to our Chief Executive Officer and each of the two other most highly compensated executive officers during 2016 (collectively, the “Named Executive Officers”).

**Summary Compensation**

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
<b>Christopher J. Schaber(1)</b>	CEO & President	2016	\$434,969	\$121,792		\$ 41,511	\$598,272
		2015	\$424,360	\$101,846	\$158,200	\$ 36,201	\$720,607
<b>Karen Krumeich(2)</b>	CFO & Senior VP	2016	\$120,250	\$23,976	\$74,000	\$ 7,849	\$226,075
		2015	-	-	-	-	-
<b>Richard C. Straube(3)</b>	CMO & Senior VP	2016	\$316,725	\$68,413		\$ 27,919	\$413,057
		2015	\$309,000	\$58,401	\$79,100	\$ 25,656	\$472,157
<b>Joseph M. Warusz(4)</b>	Former VP & Acting CFO	2016	\$151,236			\$ 20,472	\$171,708
		2015	\$196,730	\$38,362	\$62,150	\$ 24,676	\$321,918

Dr. Schaber’s 2016 bonus payment of \$121,792 was deferred until April 1, 2017. Option award figures include the (1) value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

On June 16, 2016 Ms. Krumeich was appointed Senior Vice President and Chief Financial Officer. Ms. Krumeich (2) deferred the payment of her 2016 bonus of \$23,976 until January 15, 2017. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

Dr. Straube deferred the payment of his 2016 bonus of \$68,413 until January 15, 2017. Option award figures (3) include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

Option award figures include the value of common stock option awards at grant date as calculated under FASB (4) ASC 718. Other compensation represents health insurance costs paid by the Company. Other compensation represents health insurance costs paid by the Company. On June 30, 2016, Mr. Warusz retired from the Company.

**Employment and Severance Agreements**

In August 2006, we entered into a three-year employment agreement with Christopher J. Schaber, PhD. Pursuant to this employment agreement we agreed to pay Dr. Schaber a base salary of \$300,000 per year and a minimum annual bonus of \$100,000. Dr. Schaber's employment agreement automatically renews every three years, unless otherwise terminated, and was automatically renewed in December 2007, December 2010, December 2013 and December 2016 for an additional term of three years. We agreed to issue him options to purchase 12,500 shares of our common stock, with one third immediately vesting and the remainder vesting over three years. Upon termination without "Just Cause" as defined by this agreement, we would pay Dr. Schaber nine months of severance, as well as any accrued bonuses, accrued vacation, and we would provide health insurance and life insurance benefits for Dr. Schaber and his dependents. No unvested options shall vest beyond the termination date. Dr. Schaber's monetary compensation (base salary of \$300,000 and bonus of \$100,000) remained unchanged from 2006 with the 2007 renewal. Upon a change in control of the Company due to merger or acquisition, all of Dr. Schaber's options shall become fully vested, and be exercisable for a period of five years after such change in control (unless they would have expired sooner pursuant to their terms). In the event of his death during the term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber's immediate family.

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In February 2007, our Board of Directors authorized the issuance of 5,000 shares to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of our assets are transferred from the Company and/or our stockholders to a third party. The amended agreement with Dr. Schaber includes our obligation to issue such shares to him if such event occurs.

On June 22, 2011, the Compensation Committee eliminated his fixed minimum annual bonus payable and revised it to an annual targeted bonus of 40% of his annual base salary. On December 4, 2014, the Compensation Committee approved an increase in salary for Dr. Schaber to \$424,360. On December 10, 2015, the Compensation Committee approved an increase in salary for Dr. Schaber to \$434,969. On December 14, 2016, the Compensation Committee approved an increase in salary for Dr. Schaber to \$443,668.

In May 2011, we entered into a one-year employment agreement with Mr. Joseph M. Warusz, our Acting Chief Financial Officer, Vice President Finance and Chief Accounting Officer. Pursuant to the agreement, we have agreed to pay Mr. Warusz \$175,000 per year and a targeted annual bonus of 30% of base salary. We also agreed to issue him options to purchase 4,000 shares of our common stock with one-third immediately vesting and the remainder vesting over three years. Mr. Warusz's employment agreement automatically renews each year, unless otherwise terminated, and was automatically renewed each year since execution, until Mr. Warusz retired from the Company effective June 30, 2016. In connection with his retirement, we agreed to provide Mr. Warusz three months of salary and three months of health insurance benefits and to accelerate the vesting and extend the exercise period of certain options. On December 4, 2014, the Compensation Committee approved an increase in salary for Mr. Warusz to \$196,730. On December 10, 2015, the Compensation Committee approved an increase in salary for Mr. Warusz to \$201,648. On June 30, 2016, Mr. Warusz retired from the Company. As defined in the employment agreement, we paid Mr. Warusz three months of severance, vacation, as well as insurance benefits to the term of his severance.

In December 2014, we entered into a one-year employment agreement with Richard C. Straube, MD, our Chief Medical Officer and Senior Vice President. Pursuant to the agreement, we have agreed to pay Dr. Straube \$300,000 per year and a targeted annual bonus of 30% of base salary. We also agreed to issue him options to purchase 10,000 shares of our common stock with one-third immediately vesting and the remainder vesting over three years. Dr. Straube's employment agreement automatically renews each year, unless otherwise terminated, and has automatically renewed each year since execution. Upon termination without "Just Cause", as defined in Dr. Straube's employment agreement, we would pay Dr. Straube three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 4, 2014, the Compensation Committee approved an increase in salary for Dr. Straube to \$309,000. On December 10, 2015, the Compensation Committee approved an increase in salary for Dr. Straube to \$316,725. On December 14, 2016, the Compensation Committee approved an increase in salary for Dr. Straube to \$323,060.

On June 16, 2016, we entered into a one-year employment agreement with Karen Krumeich, our Senior Vice President and Chief Financial Officer. Pursuant to the agreement, we have agreed to pay Ms. Krumeich \$222,000 per year and a targeted annual bonus of 30% of base salary. We also agreed to issue her options to purchase 10,000 shares

of our common stock with one-quarter immediately vesting and the remainder vesting over three years. Ms. Krumeich's employment agreement automatically renews each year, unless otherwise terminated. Upon termination without "Just Cause", as defined in Ms. Krumeich's employment agreement, we would pay Ms. Krumeich three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date. On December 14, 2016, the Compensation Committee approved an increase in salary for Ms. Krumeich to \$226,440.

Table of Contents**Outstanding Equity Awards at Fiscal Year-End**

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2016, as adjusted for the reverse stock split of one-for-ten effective October 7, 2016. We have never issued Stock Appreciation Rights.

Name	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable			
Christopher J. Schaber	2,500	-	-	\$ 54.00	8/9/2017
	4,500	-	-	\$ 94.00	8/9/2017
	14,000	-	-	\$ 12.00	12/17/2018
	11,000	-	-	\$ 46.40	6/30/2020
	11,219	-	-	\$ 6.40	11/30/2021
	13,000	-	-	\$ 6.80	12/04/2022
	10,000	-	-	\$ 20.10	12/04/2023
	7,500	2,500	2,500	\$ 15.00	12/04/2024
	7,000	7,000	7,000	\$ 11.30	12/30/2025
Richard C. Straube	9,375	625	625	\$ 20.10	1/06/2024
	3,754	1,246	1,246	\$ 15.00	12/04/2024
	3,502	3,498	3,498	\$ 11.30	12/30/2025
Joseph M. Warusz <sup>1</sup>	4,000	-	-	\$ 6.40	5/30/2021
	2,531	-	-	\$ 6.80	11/30/2021
	5,500	-	-	\$ 20.10	12/04/2022
	4,500	-	-	\$ 15.00	12/04/2023
	4,500	-	-	\$ 11.30	12/04/2024
	5,500	-	-	\$ 6.40	12/30/2025
Karen Krumeich	3,750	6,250	6,250	\$ 7.40	6/15/2016

<sup>1</sup> On June 30, 2016, Mr. Warusz retired from the Company and all unvested options immediately vested.

**Compensation of Directors**

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2016.

<b>Name</b>	<b>Fees Earned Paid in Cash<sup>1</sup></b>	<b>Option Awards<sup>2</sup></b>	<b>Total</b>
Keith L. Brownlie	\$55,500	\$ 30,000	\$85,000
Marco M. Brughera	\$40,000	\$ 30,000	\$70,000
Gregg A. Lapointe	\$47,500	\$ 30,000	\$77,500
Robert J. Rubin	\$52,500	\$ 30,000	\$82,500
Jerome B. Zeldis	\$50,000	\$ 30,000	\$80,000

Directors who are compensated as full-time employees receive no additional compensation for service on our Board of Directors. Each independent director who is not a full-time employee is paid \$35,000 annually, on a prorated basis, for their service on our Board of Directors, the chairman of our Audit Committee is paid \$15,000 annually, on a prorated basis, and the chairmen of our Compensation and Nominating Committees will be paid \$10,000 annually, on a prorated basis. Additionally, Audit Committee members are paid \$7,500 annually and Compensation and Nominating Committee members are paid \$5,000 annually. This compensation is paid quarterly.

We maintain a stock option grant program pursuant to the nonqualified stock option plan, whereby members of our Board of Directors or its committees who are not full-time employees receive an initial grant of fully vested options to purchase 1,500 shares of common stock. Upon re-election to the Board, each Board member will receive stock options with a value of \$30,000, calculated using the closing price of the common stock on the trading day prior to the date of the annual meeting of the Company's stockholders, which vest at the rate of 25% per quarter, commencing with the first quarter after each annual meeting of stockholders.

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**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

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

We are party to a common stock purchase agreement with Sigma-Tau Pharmaceuticals, Inc., which is now known as Leadiant Biosciences, Inc. (“Leadiant”), a corporation of which Paolo Cavazza, who at one point since January 1, 2016 beneficially owned 5% or more of the shares of our outstanding common stock, indirectly owns 37.2%. The agreement provides that Leadiant has the right to require that we register its shares under the Securities Act of 1933 (the “Securities Act”) for sale to the public, on not more than one occasion during any twelve-month rolling period, and not more than two occasions in the aggregate. We must pay all expenses incurred in connection with the exercise of these demand registration rights. Additionally, the agreement required us to use our best efforts to secure the election of a Leadiant’s designee to our Board of Directors as long as Leadiant beneficially owned at least 10% of our issued and outstanding shares of common stock. As of November 15, 2017, Leadiant beneficially owned less than 5% of our outstanding common stock, and our obligation with respect to the election of a Sigma-Tau Pharmaceuticals designee to our Board of Directors has expired.

In addition, Leadiant has piggyback registration rights, which means that they have the right to include their shares in any registration that we effect under the Securities Act, subject to specified exceptions. We must pay all expenses incurred in connection with these piggyback registration rights.

We are party to a common stock purchase agreement with SciClone Pharmaceuticals, Inc. (“SciClone”), which at one point since January 1, 2016 beneficially owned 5% or more of the shares of our outstanding common stock. Under the agreement, SciClone has demand registration rights, which means that SciClone has the right to require that we register its shares under the Securities Act for sale to the public, on not more than one occasion, subject to specified exceptions. We must pay all expenses incurred in connection with the exercise of these demand registration rights. As of November 15, 2017, SciClone beneficially owned less than 5% of our outstanding common stock.

We are party to a registration rights agreement with the Selling Stockholders, including Amir L. Ecker, who beneficially owns 5% or more of the shares of our outstanding common stock. Under the agreement, the Selling Stockholders have registration rights, and, therefore, we are registering 982,000 shares for resale by the Selling Stockholders in this offering. The Selling Stockholders also have piggyback registration rights, which means that, if not already registered, they have the right to include their shares in any registration that we effect under the Securities Act, subject to specified exceptions. We must pay all expenses incurred in connection with the exercise of these demand registration rights.

We are unable to estimate the dollar value of the registration rights to the holders of these rights. The amount of reimbursable expenses under the agreements depends on a number of variables, including whether registration rights are exercised incident to a primary offering by us, the form on which we are eligible to register such a transaction, and whether we have a shelf registration in place at the time of a future offering.

In our June 2013 public offering, we issued warrants that contained provisions protecting holders from a decline in the issue price of our common stock (or “down-round” provision) and contained net settlement provisions. As a result, we accounted for these warrants as liabilities instead of equity instruments. During November 2016, we entered into amendments with the holders of those warrants pursuant to which we agreed to reduce the exercise price (after giving effect to the one-for-ten reverse stock split effective October 7, 2016) from \$5.10 per share to \$0.80 per share and permit those warrants to be exercised on a “cashless exercise” basis, and we eliminated the “down round” provision of those warrants not immediately exercised. As a result of the amendments, the warrant liability was remeasured as of the date of the modification, which resulted in an approximate \$1,541,000 decrease in the carrying value of the warrant liability, which was recognized in the statement of operations for the year ended December 31, 2016. The warrant liability related to the warrants not immediately exercised was then reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments. Of the 303,694 shares of common stock that remained issuable upon the exercise of such warrants as of September 30, 2016, warrants to purchase a total of 250,000 shares were held by NRM VII Holdings I, LLC, an entity the manager of which is indirectly controlled by Mr. Kirk, who at the time beneficially owned 5% or more of the shares of our outstanding common stock.

Other than as described above, the employment agreements and compensation paid to our directors, we did not engage in any transactions with related parties since January 1, 2016. For a discussion of our employment agreements and compensation paid to our directors, see “Executive Compensation”.



Table of Contents**PRINCIPAL STOCKHOLDERS**

The table below provides information regarding the beneficial ownership of the common stock as of November 15, 2017, of (1) each person or entity who owns beneficially 5% or more of the shares of our outstanding common stock, (2) each of our directors, (3) each of the Named Executive Officers, and (4) our directors and officers as a group. Except as otherwise indicated, and subject to applicable community property laws, we believe the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

**Beneficial Ownership**

Name of Beneficial Owner	Shares of Common  Stock Beneficially Owned**	Percent  of Class
ACT Capital Management, LLLP <sup>(1)</sup>	872,000	9.99 %
Knoll Capital Management, LP <sup>(2)</sup>	870,000	9.96 %
Christopher J. Schaber <sup>(3)</sup>	146,940	1.66 %
Keith L. Brownlie <sup>(4)</sup>	22,624	*
Marco M. Brughera <sup>(5)</sup>	19,962	*
Gregg A. Lapointe <sup>(6)</sup>	26,254	*
Robert J. Rubin <sup>(7)</sup>	29,340	*
Jerome B. Zeldis <sup>(8)</sup>	23,707	*
Richard Straube <sup>(9)</sup>	29,004	*
Oreola Donini <sup>(10)</sup>	28,004	*
Karen Krumeich <sup>(11)</sup>	16,300	*
All directors and executive officers as a group (9 persons)	342,135	3.79 %

(1) On November 7, 2017, ACT Capital Management, LLLP, on behalf of itself and Amir L. Ecker and Carol G. Frankenfield, filed a Schedule 13G with the SEC (the "Schedule 13G"). The Schedule 13G states that Amir L. Ecker and Carol G. Frankenfield are the General Partners of ACT Capital Management, LLLP and that investment decisions made on behalf of ACT Capital Management, LLLP are made primarily by its General Partners. The Schedule 13G indicates that (a) ACT Capital Management, LLLP has sole voting and dispositive power with respect to 250,000 shares and shared dispositive power with respect 872,000 shares; (b) Amir L. Ecker has sole voting power with respect to 472,000 shares, shared voting power with respect to 325,000 shares and shared dispositive power with respect 872,000 shares and (c) Carol G. Frankenfield has sole voting power with respect to 25,000 shares, shared voting power with respect to 275,000 shares and shared dispositive power with respect 872,000 shares. The address of the principal business office of ACT Capital Management, LLLP, Amir L. Ecker

and Carol G. Frankenfield is 100 W. Lancaster Ave., Suite 110, Wayne, PA 19087.

- (2) On November 13, 2017, Knoll Capital Management, LP (“KCMLP”), on behalf of Fred Knoll and Gakasa Holdings, LLC (“Gakasa”) filed a Schedule 13G with the SEC (the “Schedule 13G”). The Schedule 13G states that KCMLP is the investment manager of Gakasa, and Fred Knoll is the President of KCMLP. The Schedule 13G indicates that KCMLP, Fred Knoll and Gakasa have shared voting and dispositive power with respect to the 870,000 shares. The address of the principal business office of KCMLP, Fred Knoll and Gakasa is 5 East 44<sup>th</sup> Street, Suite 12, New York, NY 10017.

- (3) Includes 25,095 shares of common stock owned by Dr. Schaber, options to purchase 101,594 shares of common stock exercisable within 60 days of November 15, 2017, and warrants to purchase 20,251 shares of common stock exercisable within 60 days of November 15, 2017. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540

- (4) Includes 5,000 shares of common stock and options to purchase 17,624 shares of common stock exercisable within 60 days of November 15, 2017. The address of Mr. Brownlie is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

- (5) Includes 2,750 shares of common stock, options to purchase 14,712 shares of common stock exercisable within 60 days of November 15, 2017, and warrants to purchase 2,500 shares of common stock exercisable within 60 days of November 15, 2017. The address of Dr. Brughera is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

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(6) Includes 7,379 shares of common stock and options to purchase 18,875 shares of common stock exercisable within 60 days of November 15, 2017. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(7) Includes 4,385 shares of common stock, options to purchase 20,999 shares of common stock exercisable within 60 days of November 15, 2017, and warrants to purchase 3,956 shares of common stock exercisable within 60 days of November 15, 2017. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(8) Includes 6,917 shares of common stock and options to purchase 16,790 shares of common stock exercisable within 60 days of November 15, 2017. The address of Dr. Zeldis is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(9) Includes options to purchase 29,004 shares of common stock exercisable within 60 days of November 15, 2017. The address of Dr. Straube is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(10) Includes options to purchase 23,004 shares of common stock owned by Dr. Donini exercisable within 60 days of November 15, 2017 and warrants to purchase 5,000 shares of common stock exercisable within 60 days of November 15, 2017. The address of Dr. Donini is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

(11) Includes 1,300 shares of common stock and options to purchase 15,000 shares of common stock owned by Ms. Krumeich exercisable within 60 days of November 15, 2017. The address of Ms. Krumeich is c/o Soligenix, 29 Emmons Drive, Suite B-10, Princeton, New Jersey 08540.

\* Indicates less than 1%.

Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of November 15, 2017 are deemed \*\*outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 8,730,640 shares of common stock outstanding as of November 15, 2017.

**SELLING STOCKHOLDERS**

The following table presents information as of November 15, 2017 and sets forth the number of shares of common stock beneficially owned by each of the Selling Stockholders. We are not able to estimate the amount of shares that will be held by each of the Selling Stockholders after the completion of this offering because: (1) the Selling Stockholders may sell less than all of the shares registered under this prospectus; and (2) to our knowledge, the Selling Stockholders currently have no agreements, arrangements or understandings with respect to the sale of any of their shares. The following table assumes that all of the shares being registered pursuant to this prospectus will be sold. The Selling Stockholders are not making any representation that any shares covered by this prospectus will be offered for

sale. Except as otherwise indicated, based on information provided to us by each of the Selling Stockholders, the Selling Stockholders have sole voting and investment power with respect to their shares of common stock. Except as otherwise noted, none of the Selling Stockholders nor any of their affiliates have held a position or office, or had any other material relationship, with us.

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On November 15, 2017, we completed a private placement in which we issued 982,000 shares of common stock to the Selling Stockholders, resulting in gross proceeds of \$1,964,000. In a concurrent public offering, we issued an aggregate of 1,575,500 shares of our common stock, 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. In connection with the private placement, we granted the Selling Stockholders registration rights, and, therefore, we are registering 982,000 shares for resale by the Selling Stockholders in this offering.

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Before the Offering **	Percent of Common Stock Beneficially Owned Before the Offering **		Shares Available for Sale Under This Prospectus	Number of Shares of Common Stock To Be Beneficially Owned After Completion of the Offering **	Percent of Common Stock to be Beneficially Owned After Completion of the Offering	
Gakasa Holdings, LLC	870,000	(1) 9.96	%	370,000	500,000	5.72	%
ACT Capital Partners, LP	250,000	(2) 2.86	%	250,000	-	*	
Porter Partners L.P.	300,000	(3) 3.44	%	150,000	150,000	1.72	%
Amir L. Ecker	120,000	(4) 1.37	%(4)	120,000	-	*	
W. Anthony Hitschler	114,500	1.31	%	49,000	65,500	*	
David Weiner	100,000	1.15	%	43,000	57,000	*	

\* Less than 1%.

Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of November 15, 2017, are deemed

\*\* outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 8,730,640 shares of common stock outstanding as of November 15, 2017.

- (1) KCMLP, Fred Knoll and Gakasa have shared voting and dispositive power with respect to the 870,000 shares beneficially owned by Gakasa Holdings, LLC.
- (2) Amir L. Ecker and Carol G. Frankenfield share voting and dispositive power with respect to the 250,000 shares.
- (3) Jeffrey H. Porter exercises sole voting and dispositive power with respect to the 300,000 shares.
- (4) ACT Capital Management, LLLP beneficially owns 872,000 shares of common stock, including the 120,000 shares held by Mr. Ecker, which in the aggregate represent 9.99% of the issued and outstanding shares of common stock. Mr. Ecker may be deemed a beneficial owner of the shares beneficially owned by ACT Capital Management, LLLP solely because he is a General Partner of that partnership. (a) ACT Capital Management, LLLP has sole voting and dispositive power with respect to 250,000 shares and shared dispositive power with respect 872,000 shares; (b) Amir L. Ecker has sole voting power with respect to 472,000 shares, shared voting power with respect to 325,000 shares and shared dispositive power with respect 872,000 shares and (c) Carol G. Frankenfield has sole voting power with respect to 25,000 shares, shared voting power with respect to 275,000

shares and shared dispositive power with respect 872,000 shares.

## **PLAN OF DISTRIBUTION**

The Selling Stockholders and any of their pledgees, donees, transferees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits investors;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

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

privately negotiated transactions;

to cover short sales and other hedging transactions made after the date that the registration statement of which this prospectus is a part is declared effective by the Securities and Exchange Commission;

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

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the investor of shares, from the purchaser) in amounts to be negotiated. The Selling Stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus.

The Selling Stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, that can be attributed to the sale of securities will be paid by the Selling Stockholders and/or the purchasers of the securities.

Each Selling Stockholder that is affiliated with a registered broker-dealer has confirmed to us that, at the time it acquired the securities subject to the registration statement of which this prospectus is a part, it did not have any agreement or understanding, directly or indirectly, with any person to distribute any of such securities. The Company has advised each Selling Stockholder that it may not use shares registered on the registration statement of which this prospectus is a part to cover short sales of our common stock made prior to the date on which such registration statement was declared effective by the SEC.

We are required to pay certain fees and expenses incident to the registration of the shares. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the Selling Stockholders without registration and without regard to any volume limitations by reason of Rule 144(b)(1) under the Securities Act or any other rule of similar effect and (ii) such time as all of the shares have been publicly sold.



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**DESCRIPTION OF CAPITAL STOCK**

As of the date hereof, our authorized capital stock consists of 25,350,000 shares of capital stock, of which 25,000,000 shares are common stock, par value \$0.001 per share, 230,000 shares are undesignated preferred stock, 10,000 shares are Series B Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding), 10,000 shares are Series C Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding) and 100,000 shares are Series A Junior Participating Preferred Stock, par value \$0.001 per share (which are available for issuance under our shareholder rights plan). As of the date of this prospectus, there were issued and outstanding 8,730,640 shares of common stock, options to purchase 510,055 shares of common stock and warrants to purchase 2,654,725 shares of common stock.

**Common Stock**

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

**Preferred Stock**

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

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

*Series B Preferred Stock*

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

*Voting*

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

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### *Dividends*

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

### *Conversion*

Each share of Series B Cumulative Convertible Preferred is convertible into 1.333 shares of common stock. The conversion ratio is subject to an adjustment upon the issuance of additional shares of common stock for a price below the closing price of the common stock and equitable adjustment for stock splits, dividends, combinations, reorganizations and similar events.

### *Liquidation*

In the event of liquidation, dissolution or winding up of the company, the holders of Series B Preferred Stock then outstanding will be entitled to be paid an amount equal to \$1,000 per share (subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares pursuant to our Certificate of Incorporation), plus any dividends declared but unpaid thereon before any payment is made to the holders of common stock, Junior Preferred Stock or any other class or series of stock ranking on liquidation junior to the Series B Preferred Stock. After the holders of the Series B Preferred Stock have been paid in full, the remaining assets of the company will be distributed to the holders of Junior Preferred Stock and common stock, subject to the preferences of the Junior Preferred Stock.

### *Redemption*

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

## *Junior Preferred Stock*

### *Voting*

The holders of the Junior Preferred Stock will have 10,000 votes per share of Junior Preferred Stock on all matters submitted to a vote of our stockholders, including the election of directors.

### *Dividends*

If our board of directors declares or pays dividends on common stock, the holders of the Junior Preferred Stock would be entitled to receive a per share dividend payment of 10,000 times the dividend declared per share of common stock. In the event we make a distribution on the common stock, the holders of the Junior Preferred Stock will be entitled to a per share distribution, in like kind, of 10,000 times such distribution made per share of common stock. In the event of any merger, consolidation or other transaction in which shares of common stock are exchanged, each share of Junior Preferred Stock will be entitled to receive 10,000 times the amount received per share of common stock. These rights are protected by customary anti-dilution provisions.

### *Liquidation*

Upon any liquidation, dissolution or winding up, no distribution may be made to the holders of shares of stock ranking junior to the Junior Preferred Stock unless the holders of the Junior Preferred Stock have received the greater of (i) \$37.00 per one one-thousandth share plus an amount equal to accrued and unpaid dividends and distributions thereon, and (ii) an amount equal to 10,000 times the aggregate amount to be distributed per share to holders of common stock. Further, no distribution may be made to the holders of stock ranking on a parity upon liquidation, dissolution or winding up with the Junior Preferred Stock, unless distributions are made ratably on the Junior Preferred Stock and all other shares of such parity stock in proportion to the total amounts to which the holders of the Junior Preferred Stock are entitled above and to which the holders of such parity shares are entitled.

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**Outstanding Warrants**

***2013 Warrants***

On June 25, 2013, we consummated a public offering of an aggregate of 677,400 shares of common stock, together with warrants to purchase up to 508,050 shares of common stock. In connection with the offering, we also issued the placement agent a warrant to purchase up to 33,609 shares of common stock. Such warrants may be exercised on a “cashless” basis. We refer to the warrants issued to the investors and the placement agent in connection with the offering as the “2013 Warrants.”

As of November 15, 2017, 11,750 shares of common stock remain issuable upon the exercise of the 2013 Warrants, which expire in June 2018.

As of November 15, 2017, the 2013 Warrants were exercisable to purchase shares of common stock at \$0.80 per share. The exercise price and the number of shares of common stock purchasable upon the exercise of each 2013 Warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

***2014 Warrants***

On December 24, 2014, we consummated a public offering of an aggregate of 188,653 shares of common stock, together with warrants to purchase up to 113,192 shares of common stock. In connection with the offering, we also issued the underwriter a warrant to purchase up to 3,740 shares of common stock. We refer to the warrants issued to the investors and the underwriter in connection with the offering as the “2014 Warrants.”

As of November 15, 2017, 110,932 shares of common stock remain issuable upon the exercise of the 2014 Warrants, which expire in 2019.

As of November 15, 2017, the 2014 Warrants were exercisable to purchase shares of common stock at \$14.80 per share. The exercise price and the number of shares of common stock purchasable upon the exercise of each 2014 Warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

***2016 Warrants***

On December 16, 2016, we consummated a public offering of an aggregate of 1,670,000 shares of common stock, together with warrants to purchase up to 2,370,005 shares of common stock. In connection with the offering, we also issued the underwriter a warrant to purchase up to 33,400 shares of common stock. We refer to the warrants issued to the investors and the underwriter in connection with the offering as the “2016 Warrants.”

As of November 15, 2017, 2,403,405 shares of common stock remain issuable upon the exercise of the 2016 Warrants. The 2016 Warrants issued to investors were exercisable upon issuance and expire in 2021, and the 2016 Warrants issued to the underwriter will become exercisable in December 2017 and will expire in 2021.

As of November 15, 2017, the exercise price of the 2016 Warrants was \$3.95 per share. The exercise price and the number of shares of common stock purchasable upon the exercise of each 2016 Warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

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***Other Warrants***

As of November 15, 2017, we also had outstanding warrants, other than the 2013 Warrants, the 2014 Warrants and the 2016 Warrants, to purchase (a) 77,488 shares of common stock, all of which are exercisable at a weighted average exercise price of approximately \$5.58 per share, and (b) 51,150 shares of common stock, which become exercisable on May 1, 2018 at an exercise price of \$2.50 per share.

**Delaware Anti-Takeover Statute**

We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

prior to the date of the transaction, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, calculated as provided under Section 203; or

at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

**Anti-Takeover Provisions**

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

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

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

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

### **Transfer Agent**

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

### **Listing**

Our common stock and the 2016 Warrants are listed on The Nasdaq Capital Market under the symbols "SNGX" and "SNGXW," respectively.



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

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

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

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

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

**LEGAL MATTERS**

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

**EXPERTS**

The consolidated balance sheets of Soligenix, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity (deficiency), and cash flows for each of the years then ended, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is included herein. Such financial statements have been included herein in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

## **WHERE YOU CAN FIND MORE INFORMATION**

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

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

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

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

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

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**SOLIGENIX, INC. AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

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Table of Contents**Soligenix, Inc. and Subsidiaries****Consolidated Balance Sheets**

	<b>September 30, 2017</b>	<b>December 31, 2016</b>
	(Unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$4,999,153	\$8,772,567
Contracts and grants receivable	634,871	1,206,777
Prepaid expenses	120,593	134,431
Total current assets	5,754,617	10,113,775
Office furniture and equipment, net	16,997	26,702
Intangible assets, net	80,818	126,628
Total assets	\$5,852,432	\$10,267,105
 Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$1,477,660	\$1,708,091
Accrued expenses	1,091,263	806,118
Accrued compensation	138,687	355,648
Total current liabilities	2,707,610	2,869,857
 Commitments and contingencies		
 Shareholders' equity:		
Preferred stock, 350,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 25,000,000 and 10,000,000 shares authorized at September 30, 2017 and December 31, 2016, respectively; 5,922,896 shares and 5,470,032 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	5,923	5,470
Additional paid-in capital	158,269,990	157,514,740
Accumulated deficit	(155,131,091)	(150,122,962)
Total shareholders' equity	3,144,822	7,397,248
Total liabilities and shareholders' equity	\$5,852,432	\$10,267,105

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

Table of Contents**Soligenix, Inc. and Subsidiaries****Consolidated Statements of Operations****For the Three and Nine Months Ended September 30, 2017 and 2016****(Unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Revenues				
Contract revenue	\$1,395,234	\$2,959,254	\$3,717,089	\$8,750,291
Grant revenue	426,832	-	426,832	-
Total revenues	1,822,066	2,959,254	4,143,921	8,750,291
Cost of revenues	(1,474,151)	(2,630,046)	(3,238,633)	(7,204,920)
Gross profit	347,915	329,208	905,288	1,545,371
Operating expenses:				
Research and development	605,719	1,177,263	3,606,973	3,433,595
General and administrative	711,819	650,762	2,322,957	2,526,255
Total operating expenses	1,317,538	1,828,025	5,929,930	5,959,850
Loss from operations	(969,623 )	(1,498,817)	(5,024,642)	(4,414,479)
Other income (expense):				
Change in fair value of warrant liability	-	(176,293 )	-	1,109,192
Other income (expense)	(789 )	-	(789 )	390,599
Interest income (expense)	7,318	1,893	17,302	(736 )
Total other income (expense)	6,529	(174,400 )	16,513	1,499,055
Net loss	\$(963,094 )	\$(1,673,217)	\$(5,008,129)	\$(2,915,424)
Basic net loss per share	\$(0.17 )	\$(0.49 )	\$(0.89 )	\$(0.90 )
Diluted net loss per share	\$(0.17 )	\$(0.49 )	\$(0.89 )	\$(1.20 )
Basic weighted average common shares outstanding	5,757,973	3,432,081	5,610,767	3,245,653
Diluted weighted average common shares outstanding	5,757,973	3,432,081	5,610,767	3,347,837

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

Table of Contents**Soligenix, Inc. and Subsidiaries****Consolidated Statement of Changes in Shareholders' Equity****For the Nine Months Ended September 30, 2017****(Unaudited)**

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2016	5,470,032	\$5,470	\$157,514,740	\$(150,122,962)	\$7,397,248
Issuance of common stock pursuant to Lincoln Park Equity Line	50,483	50	115,880	-	115,930
Issuance of common stock pursuant to FBR At-the-Market Sales Agreement	199,756	200	451,770	-	451,970
Costs associated with FBR At-the-Market Sales Agreement	-	-	(146,878 )	-	(146,878 )
Issuance of common stock from cashless exercise of warrants	200,125	200	(200 )	-	-
Issuance of common stock to vendors	2,500	3	5,922	-	5,925
Share-based compensation expense	-	-	328,756	-	328,756
Net loss	-	-	-	(5,008,129 )	(5,008,129)
Balance, September 30, 2017	5,922,896	\$5,923	\$158,269,990	\$(155,131,091)	\$3,144,822

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

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

	<b>2017</b>	<b>2016</b>
Operating activities:		
Net loss	\$(5,008,129)	\$(2,915,424)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	57,647	67,902
Amortization of discount on debt	-	7,281
Share-based compensation	328,756	453,935
Gain on settlement of liability	-	(390,599 )
Issuance of common stock for services	5,925	52,500
Change in fair value of warrant liability	-	(1,109,192)
Change in operating assets and liabilities:		
Contracts and grants receivable	571,906	287,580
Prepaid expenses	13,838	18,653
Accounts payable and accrued expenses	54,714	206,881
Accrued compensation	(216,961 )	(236,430 )
Total adjustments	815,825	(641,489 )
Net cash used in operating activities	(4,192,304)	(3,556,913)
Investing activities:		
Purchases of office furniture and equipment	(2,132 )	(7,161 )
Net cash used in investing activities	(2,132 )	(7,161 )
Financing activities:		
Proceeds from issuance of common stock pursuant to the equity line	115,930	1,639,110
Stock issuance costs associated with equity line purchase agreement	-	(41,381 )
Repayment of notes payable	-	(300,000 )
Proceeds from issuance of common stock to SciClone	-	3,000,000
Proceeds from issuance of common stock pursuant to FBR At-the-Market Sales Agreement	451,970	-
Costs associated with FBR At-the-Market Sales Agreement	<b>(146,878 )</b>	-
Net cash provided by financing activities	421,022	4,297,729
Net increase (decrease) in cash and cash equivalents	(3,773,414)	733,655
Cash and cash equivalents at beginning of period	8,772,567	4,921,545
Cash and cash equivalents at end of period	\$4,999,153	\$5,655,200



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

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**Soligenix, Inc.**

**Notes to Consolidated Financial Statements**

**(Unaudited)**

**Note 1. Nature of Business**

Basis of Presentation

Soligenix, Inc. (the “Company”) is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense.

The Company’s 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”), its first-in-class innate defense regulator (“IDR”) 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).

The Company’s Vaccines/BioDefense business segment includes active development programs for RiVax<sup>®</sup>, its ricin toxin vaccine candidate, OrbeShield<sup>®</sup>, a GI acute radiation syndrome (“GI ARS”) therapeutic candidate and SGX943, a therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of the vaccine program is currently supported by the heat stabilization technology, known as ThermoVax<sup>®</sup>, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases (“NIAID”), the Company will attempt to advance the development of RiVax<sup>®</sup> to protect against exposure to ricin toxin. The Company has advanced the development of OrbeShield<sup>®</sup> for the treatment of GI ARS with funds received under its awarded government contracts with the Biomedical Advanced Research and Development Authority (“BARDA”) and NIAID. The Company will continue to pursue additional government funding support.

The Company generates revenues under government grants primarily from the National Institutes of Health (“NIH”) and government contracts from BARDA and NIAID. The Company is currently developing RiVax<sup>®</sup> under a NIH contract of up to \$24.7 million over six years, and SGX301 and SGX942 under two separate NIH grants of approximately \$1.5 million each over two years. The NIAID contract for the development of OrbeShield<sup>®</sup> was completed 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. The Company will continue to apply for additional government funding.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with the United States Food and Drug Administration (the U.S. "FDA") regulations, and other regulatory authorities, litigation, and product liability. Results for the three and nine months ended September 30, 2017 are not necessarily indicative of results that may be expected for the full year.

### Liquidity

In accordance with Accounting Standards Codification 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of September 30, 2017, the Company had an accumulated deficit of \$155,131,091. During the nine months ended September 30, 2017, the Company incurred a net loss of \$5,008,129 and used \$4,192,304 of cash in operations. The Company expects to continue to generate losses in the foreseeable future. The Company's liquidity needs will be largely determined by the budgeted operational expenditures incurred in regards to the progression of its product candidates. The Company's plans to meet its liquidity needs primarily include its ability to control the timing and spending on its research and development programs and raising additional funds through potential partnerships and/or financings. Based on the Company's approved operating budget, management believes that it will have sufficient capital to meet the anticipated cash needs for working capital and capital expenditures through at least December 31, 2018. Based on the Company's current rate of cash outflows, cash on hand, proceeds from government contract and grant programs, proceeds available from the equity line with Lincoln Park Capital Fund, LLC ("Lincoln Park"), proceeds remaining from the sale of the Company's common stock pursuant to the At-the-Market ("ATM") Sales Agreement with FBR Capital Markets & Co. ("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 through at least December 31, 2018.

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As of September 30, 2017, the Company 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, the Company 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 is primarily related to expenditures to support the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL and expenditures incurred in preparation and initiation of the Phase 3 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer.

Management's business strategy can be outlined as follows:

Complete enrollment and report preliminary results in the 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<sup>®</sup> in combination with the Company's ThermoVax<sup>®</sup> technology, to develop new heat stable vaccines in biodefense with NIAID support;

Advance the preclinical and manufacturing development of OrbeShield<sup>®</sup> 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 the Company's BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;

Pursue business development opportunities for the Company's pipeline programs, as well as explore merger/acquisition strategies; and

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

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

The Company has up to \$20.6 million in active government contract and grant funding still available to support its 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. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies;

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

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

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

The Company has \$10.2 million available from an equity facility expiring in March 2019;

The Company has \$4.3 million remaining from the ATM agreement with FBR; and

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

## Reverse Stock Split

On October 7, 2016, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of one-for-ten, whereby every ten shares of its common stock was exchanged for one share of its common stock. The Company's common stock began trading on the OTCQB on a reverse split basis at the market opening on October 7, 2016. All share and per share data have been restated to reflect this reverse stock split.

## **Note 2. Summary of Significant Accounting Policies**

### Principles of Consolidation

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

### Operating Segments

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Contracts and Grants Receivable

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

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### Intangible Assets

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

The Company did not capitalize any patent related costs during the nine months ended September 30, 2017 and 2016.

### Impairment of Long-Lived Assets

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

The Company did not record any impairment of long-lived assets for the nine months ended September 30, 2017 and 2016.

### Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement



date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on September 30, 2017. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

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

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

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

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

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The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, contracts and grants receivable, accounts payable, accrued expenses, and accrued compensation approximate their fair value based on the short-term maturity of these instruments.

## Revenue Recognition

The Company's 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 the Company incurs 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

The Company 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. The Company evaluated the provisions and determined that the warrants issued in connection with the Company's June 2013 registered public offering contains provisions that protect holders from a decline in the issue price of the Company's 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, the Company 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. 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, the Company issues 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.

For the nine months ended September 30, 2017 and 2016, the Company issued stock options at a weighted average exercise price of \$2.55 and \$7.72 per share, respectively. The fair value of options issued during the nine months ended September 30, 2017 and 2016 were estimated using the Black-Scholes option-pricing model and the following assumptions:

a dividend yield of 0%;  
an expected term of 4 years;  
volatility of 90% - 93% for 2017 and 116% - 121% for 2016;  
forfeitures at a rate of 12%; and  
risk-free interest rates ranging from 1.60% - 1.81% for 2017 and 0.96% - 1.52% for 2016.

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 is 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.

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	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Numerator:				
Net loss for basic earnings per share	\$ (963,094 )	\$ (1,673,217)	\$ (5,008,129)	\$ (2,915,424)
Less change in fair value of warrant liability	-	-	-	1,109,192
Net loss for diluted earnings per share	(963,094 )	(1,673,217)	(5,008,129)	(4,024,616)
Denominator:				
Weighted-average basic common shares outstanding	<b>5,757,973</b>	3,432,081	<b>5,610,767</b>	3,245,653
Assumed conversion of dilutive securities:				
Common stock purchase warrants	-	-	-	102,184
Denominator for diluted earnings per share – adjusted weighted-average shares	<b>5,757,973</b>	3,432,081	<b>5,610,767</b>	3,347,837
Basic net loss per share	\$ (0.17 )	\$ (0.49 )	\$ (0.89 )	\$ (0.90 )
Diluted net loss per share	\$ (0.17 )	\$ (0.49 )	\$ (0.89 )	\$ (1.20 )

The following table summarizes potentially dilutive adjustments to the weighted average number of common shares which were excluded from the calculation because their effect would be anti-dilutive.

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Common stock purchase warrants	2,603,575	492,614	2,603,575	188,920
Stock options	510,055	299,752	510,055	299,752
Total	3,113,630	792,366	3,113,630	488,672

The weighted average exercise price of the Company's stock options and warrants outstanding at September 30, 2017 were \$9.93 and \$4.45 per share, respectively, and at September 30, 2016 were \$18.20 and \$7.38 per share, respectively.

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.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, “Leases” (topic 842). The FASB issued this update to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The updated guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption of the update is permitted. The Company is evaluating the impact of the adoption of this update on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting,” which amends ASC Topic 718, and intends to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. It is effective for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. The Company adopted this standard effective January 1, 2017, and elected not to change its accounting policy with respect to the estimation of forfeitures. As a result, there was no material impact to the financial statements.

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In July 2017, the FASB issued ASU No. 2017-11, *(Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. The new standard applies to issuers of financial instruments with down-round features. A down-round provision is a term in an equity-linked financial instrument (i.e. a freestanding warrant contract or an equity conversion feature embedded within a host debt or equity contract) that triggers a downward adjustment to the instrument's strike price (or conversion price) if equity shares are issued at a lower price (or equity-linked financial instruments are issued at a lower strike price) than the instrument's then-current strike price. The purpose of the feature is typically to protect the instrument's counterparty from future issuances of equity shares at a more favorable price. The ASU amends (1) the classification of such instruments as liabilities or equity by revising the certain guidance relative to evaluating if they must be accounted for as derivative instruments and (2) the guidance on recognition and measurement of freestanding equity-classified instruments. For the Company, this ASU is effective January 1, 2019, with early adoption permitted. The Company is evaluating the impact of the adoption of this update on its consolidated financial statements and related disclosures.

**Note 3. Intangible Assets**

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

	Cost	Accumulated Amortization	Net Book Value
<u>September 30, 2017</u>			
Licenses	\$462,234	\$ 381,416	\$80,818
Patents	1,893,185	1,893,185	-
Total	\$2,355,419	\$ 2,274,601	\$80,818
<u>December 31, 2016</u>			
Licenses	\$462,234	\$ 361,044	\$101,190
Patents	1,893,185	1,867,747	25,438
Total	\$2,355,419	\$ 2,228,791	\$126,628

Amortization expense was \$14,963 and \$15,589 for the three months ended September 30, 2017 and 2016, respectively, and \$45,810 and \$46,424 for the nine months ended September 30, 2017 and 2016, respectively.

Based on the balance of licenses and patents at September 30, 2017, future amortization expense is expected to be as follows:



	Amortization Expense
October 1 thru December 31, 2017	\$ 15,990
2018	\$ 37,300
2019	\$ 27,528

License fees and royalty payments are expensed as incurred as the Company does not attribute any future benefits to such payments.

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Table of Contents**Note 4. Accrued Expenses**

The following is a summary of the Company's accrued expenses:

	September 30, 2017	December 31, 2016
Clinical trial expenses	\$ 959,481	\$ 741,174
Other	131,782	64,944
Total	\$ 1,091,263	\$ 806,118

**Note 5. Notes Payable**

On July 29, 2015, the Company entered into equity purchase agreements (the "Equity Line Purchase Agreements") and registration rights agreements with certain accredited institutional investors. In consideration for entering into the Equity Line Purchase Agreements, the Company issued to the investors promissory notes having an aggregate principal amount of \$300,000, which were recorded as stock issuance costs. The promissory notes had an issuance date present value of \$282,071 and were paid on April 15, 2016. The promissory notes did not include terms for interest, therefore the interest was imputed at 9%. The discount was being accreted over the term of the promissory notes using the effective interest rate method.

**Note 6. Warrant Liability**

On June 25, 2013, the Company consummated a public offering in which the Company issued shares of common stock, together with warrants to purchase shares of common stock. These warrants contained provisions that protected holders from a decline in the issue price of its common stock (or "down-round" provision) and contained net settlement provisions. As a result, the Company accounted for these warrants as liabilities instead of equity instruments. Down-round provisions reduce the exercise or conversion price of a warrant if the Company issues equity shares for a price that is lower than the exercise or conversion price of the warrants. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of exercising the warrant by paying cash. The Company evaluates whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or the number of shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a "fixed for fixed" option. As a result of the Company's December 2014 registered public unit offering, the exercise price of warrants outstanding in connection with the public offering completed in June 2013 was adjusted to \$6.10 per share. As a result of the Company's December 2015 drawings on the Equity Line Purchase Agreements, the exercise price of warrants outstanding in connection with the public offering

conducted in June 2013 was adjusted to \$5.10 per share. The Company recognized these warrants as liabilities at their fair value on the date of grant and remeasured them to fair value on each reporting date.

During the year ended December 31, 2016, the Company 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.

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The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3) for the nine months ended September 30, 2016:

	<b>December 31, 2015</b>	<b>Decrease from Warrants Exercised in 2016</b>	<b>Decrease in Fair Value</b>	<b>September 30, 2016</b>
Warrant liability	\$ 2,434,101	-	\$ 1,109,192	\$ 1,324,909

**Note 7. Income Taxes**

The Company had gross NOLs at December 31, 2016 of approximately \$93,635,000 for federal tax purposes and approximately \$3,233,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which will begin to expire in 2018. In addition, the Company has \$6,374,000 of various tax credits which expire from 2018 to 2035. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code (“IRC”) Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carry forwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries file income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. During the year ended December 31, 2016, in accordance with the State of New Jersey’s Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused NOL carry forwards to other New Jersey-based corporate taxpayers, the Company sold New Jersey NOL carry forwards, resulting in the recognition of \$530,143 of income tax benefit, net of transaction costs. There can be no assurance as to the continuation or magnitude of this program in the future.

The Company has no tax provision for the three and nine month periods ended September 30, 2017 and 2016 due to losses incurred and the recognition of full valuation allowances recorded against net deferred tax assets.

**Note 8. Shareholders’ Equity**

Preferred Stock

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

Common Stock

During the nine months ended September 30, 2017, the Company issued the following shares of common stock:

On January 3, 2017, the Company issued 2,500 shares to a vendor for partial consideration for services performed. The fair value of the fully vested shares was \$2.37 per share;

On May 4, 2017, warrants to purchase a total of 250,000 shares were exercised on a cashless basis and as a result 200,125 shares of common stock were issued;

On May 24, 2017, the Company issued 10,096 shares of common stock pursuant to the equity line with Lincoln Park;

In July 2017, the Company issued 40,387 shares of common stock pursuant to the equity line with Lincoln Park;

Between August 14 and September 30, 2017, the Company issued FBR 199,756 shares of common stock pursuant to the ATM agreement.

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In March 2016, the Company entered into a common stock purchase agreement with Lincoln Park. The 2016 Lincoln Park equity facility allows the Company to require Lincoln Park to purchase up to 10,000 shares (“Regular Purchase”) of the Company’s common stock every two business days, up to an aggregate of \$12.0 million over approximately a 36-month period with such amounts increasing as the quoted stock price increases. The Regular Purchase may be increased up to 15,000 shares of common stock if the closing price of the common shares is not below \$10.00, up to 20,000 shares of common stock if the closing price of the common shares is not below \$15.00 and up to 25,000 shares of common stock if the closing price of the common shares is not below \$20.00. The purchase price for the Regular Purchase shall be equal to the lesser of (i) the lowest sale price of the common shares during the purchase date, or (ii) the average of the three lowest closing sale prices of the common shares during the twelve business days prior to the purchase date. Each Regular Purchase shall not exceed \$750,000. Furthermore, for each purchase by Lincoln Park, additional commitment shares in commensurate amounts up to a total of 50,000 shares will be issued based upon the relative proportion of the aggregate amount of \$12.0 million. In addition to the Regular Purchase and provided that the closing price of the common shares is not below \$7.50 on the purchase date, the Company in its sole discretion may direct Lincoln Park on each purchase date to purchase on the next stock trading day (“Accelerated Purchase Date”) additional shares of Company stock up to the lesser of (i) three times the number of shares purchased following a Regular Purchase or (ii) 30% of the trading volume of shares traded on the Accelerated Purchase Date at a price equal to the lesser of the closing sale price on the Accelerated Purchase Date or 95% of the Accelerated Purchase Date’s volume weighted average price. At September 30, 2017, the Company has \$10.2 million available from this equity line which expires in March 2019.

On August 11, 2017, the Company entered into an At Market Issuance Sales Agreement with FBR to sell shares of the Company’s 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 acts as sales agent. Under the Sales Agreement, the Company sets 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. The Sales Agreement provides that FBR is 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. The offering costs incurred to register the shares pursuant to the Sales Agreement was approximately \$131,000. The Company has no obligation to sell any shares under the Sales Agreement, and may suspend solicitation and offers under the Sales Agreement. The shares are issued pursuant to the Company’s shelf registration statement on Form S-3 and the Prospectus Supplement filed August 11, 2017 with the U.S. Securities and Exchange Commission in connection with the offer and sale of the shares pursuant to the Sales Agreement. At September 30, 2017, the Company had \$4.3 million gross proceeds remaining to be sold under this Sales Agreement which expires August 2020.

**Note 9. Commitments and Contingencies**

The Company has commitments of approximately \$425,000 as of September 30, 2017 for several licensing agreements with consultants and universities. Additionally, the Company has 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 milestones or royalty payments have

been paid or accrued.

In December 2014, the Company 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 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.

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On September 3, 2014, the Company entered into an asset purchase agreement with Hy Biopharma, Inc. (“Hy Biopharma”) pursuant to which the Company 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, the Company paid \$275,000 in cash and issued 184,912 shares of common stock with a fair value based on the Company’s stock price on the date of grant 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 the Company’s 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, the Company will be required to make additional payments of up to \$10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company provided they do not exceed 19.9% ownership of the Company’s outstanding stock. As of September 30, 2017, no milestones or royalty payments have been paid or accrued.

In February 2007, the Company’s Board of Directors authorized the issuance of 5,000 shares of the Company’s common stock to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party. Dr. Schaber’s amended employment agreement includes the Company’s obligation to issue such shares if such event occurs.

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

<b>Year</b>	<b>Research and Development</b>	<b>Property and Other Leases</b>	<b>Total</b>
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



Table of Contents**Note 10. Operating Segments**

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

	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2017</b>	<b>2016</b>
Contract/Grant Revenue		
Vaccines/BioDefense	\$1,395,234	\$2,959,254
BioTherapeutics	426,832	-
Total	\$1,822,066	\$2,959,254
Income (Loss) from Operations		
Vaccines/BioDefense	\$48,840	\$239,012
BioTherapeutics	(161,463 )	(908,086 )
Corporate	(857,000 )	(829,743 )
Total	\$(969,623 )	\$(1,498,817)
Amortization and Depreciation Expense		
Vaccines/BioDefense	\$9,279	\$10,090
BioTherapeutics	7,792	10,313
Corporate	905	2,063
Total	\$17,976	\$22,466
Other Income (Expense), Net		
Corporate	\$6,529	\$(174,400 )
Share-Based Compensation		
Vaccines/BioDefense	\$11,303	\$25,164
BioTherapeutics	22,827	30,496
Corporate	53,952	61,590
Total	\$88,082	\$117,250

Table of Contents**Nine Months Ended****September 30,  
2017                      2016**

Contract/Grant Revenue		
Vaccines/BioDefense	\$3,717,089	\$8,750,291
BioTherapeutics	426,832	-
Total	4,143,921	\$8,750,291
Income (Loss) from Operations		
Vaccines/BioDefense	\$382,710	\$1,291,123
BioTherapeutics	(2,763,279)	(2,822,766)
Corporate	(2,644,073)	(2,882,836)
Total	\$(5,024,642)	\$(4,414,479)
Amortization and Depreciation Expense		
Vaccines/BioDefense	\$28,659	\$30,150
BioTherapeutics	25,436	31,309
Corporate	3,552	6,443
Total	57,647	\$67,902
Other Income, Net		
Corporate	\$16,513	\$1,499,055
Share-Based Compensation		
Vaccines/BioDefense	44,274	77,393
BioTherapeutics	95,424	96,313
Corporate	189,058	280,229
Total	\$328,756	\$453,935

	<b>As of</b>	<b>As of</b>
	<b>September 30,</b>	<b>December 31,</b>
	<b>2017</b>	<b>2016</b>

Identifiable Assets		
Vaccines/BioDefense	\$ 649,268	\$ 1,297,986
BioTherapeutics	75,327	49,422
Corporate	5,127,837	8,919,698
Total	\$ 5,852,432	\$ 10,267,105

**Note 11. Subsequent Events**

On October 31, 2017, the Company entered into a securities purchase agreement with certain accredited investors pursuant to which the Company agreed to issue and sell an aggregate of 1,575,500 shares (the “Public Offering Shares”) of its common stock, par value \$0.001 per share, in a registered direct offering (the “Public Offering”). The Public Offering Shares were offered by the Company pursuant to its shelf registration statement on Form S-3 (“the Registration Statement”) initially filed with the Securities and Exchange Commission on May 5, 2017 (which was declared effective on August 11, 2017).

In a concurrent private placement, the Company also agreed, pursuant to additional securities purchase agreements, to issue and sell to certain of the purchasers of the Public Offering an aggregate of 982,000 shares (the “Private Placement Shares”) of common stock (the “Private Placement”). The offer and sale of the Private Placement Shares are not being registered under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to the Registration Statement. Also on October 31, 2017, the Company entered into registration rights agreements with the purchasers in the Private Placement, pursuant to which the Company agreed to file with the Commission a registration statement to register for resale under the Securities Act the Private Placement Shares.

The per share purchase price for the Public Offering Shares and the Private Placement Shares was \$2.00. The per share closing price of the common stock on October 30, 2017 was \$1.84. The closing of the offerings occurred on November 3, 2017. The gross proceeds from the offerings were \$5.1 million. The Company expects the aggregate net proceeds from the offerings, after deducting the placement agents’ fees and other estimated offering expenses, to be approximately \$4.6 million.

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

	2016	2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$8,772,567	\$4,921,545
Contracts and grants receivable	1,206,777	1,985,212
Prepaid expenses	134,431	244,267
Total current assets	10,113,775	7,151,024
Office furniture and equipment, net	26,702	47,366
Intangible assets, net	126,628	188,732
Total assets	\$10,267,105	\$7,387,122
Liabilities and shareholders' equity (deficiency)		
Current liabilities:		
Accounts payable	\$1,708,091	\$2,869,392
Accrued expenses	806,118	1,510,544
Notes payable	-	292,719
Warrant liability	-	2,434,101
Accrued compensation	355,648	298,675
Total current liabilities	2,869,857	7,405,431
Commitments and contingencies		
Shareholders' equity (deficiency):		
Preferred stock: 350,000 shares authorized; none issued or outstanding	-	-
Common stock, \$.001 par value; 10,000,000 shares and 5,000,000 shares authorized at December 31, 2016 and 2015, respectively; 5,470,032 and 3,126,952 shares issued and outstanding in 2016 and 2015, respectively	5,470	3,127
Additional paid-in capital <sup>(1)</sup>	157,514,740	146,856,143
Accumulated deficit	(150,122,962)	(146,877,579)
Total shareholders' equity (deficiency)	7,397,248	(18,309 )
Total liabilities and shareholders' equity (deficiency)	\$10,267,105	\$7,387,122

(1) Adjusted to reflect the reverse stock split of one-for-ten effective October 7, 2016.

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

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

	2016	2015
Revenues:		
Contract revenue	\$10,448,794	\$8,641,348
Grant revenue	-	127,042
Total revenues	10,448,794	8,768,390
Cost of revenues	(8,433,671 )	(6,882,204)
Gross profit	2,015,123	1,886,186
Operating expenses:		
Research and development	4,295,867	5,399,839
General and administrative	3,428,838	3,596,623
Total operating expenses	7,724,705	8,996,462
Loss from operations	(5,709,582 )	(7,110,276)
Other income (expense):		
Change in fair value of warrant liability	1,541,241	(1,201,870)
Gain on settlement of liability	390,599	-
Interest income (expense)	2,216	(8,017 )
Total other income (expense)	1,934,056	(1,209,887)
Net loss before income taxes	(3,775,526 )	(8,320,163)
Income tax benefit	530,143	488,933
Net loss	\$(3,245,383 )	(7,831,230)
Basic net loss per share <sup>(1)</sup>	\$(0.93 )	\$(3.00 )
Diluted net loss per share <sup>(1)</sup>	\$(1.34 )	\$(3.00 )
Basic weighted average common shares outstanding <sup>(1)</sup>	3,481,460	2,606,577
Diluted weighted average common shares outstanding <sup>(1)</sup>	3,583,587	2,606,577

(1) Adjusted to reflect the reverse stock split of one-for-ten effective October 7, 2016.

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

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Soligenix, Inc. and Subsidiaries  
Consolidated Statements of Changes in Shareholders' Equity (Deficiency)  
For the Years Ended December 31, 2016 and 2015

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2014	2,393,657	\$2,394	\$138,890,066	\$(139,046,349)	\$(153,889 )
Issuance of common stock pursuant to Lincoln Park Equity line	84,135	84	1,339,093	-	1,339,177
Issuance of common stock pursuant to Equity Line Purchase Agreement	454,577	455	2,499,545	-	2,500,000
Stock issuance costs associated with Equity Line Purchase Agreement	-	-	(453,162 )	-	(453,162 )
Issuance of common stock to vendors	16,628	16	232,196	-	232,212
Issuance of shares from exercise of stock options	3,312	3	19,247	-	19,250
Issuance of shares for exercise of warrants	174,643	175	1,117,346	-	1,117,521
Reclassification of warrant liability upon partial exercise of warrants issued in unit offering	-	-	2,557,331	-	2,557,331
Share-based compensation expense	-	-	654,481	-	654,481
Net loss	-	-	-	(7,831,230 )	(7,831,230)
Balance, December 31, 2015	3,126,952	\$3,127	\$146,856,143	\$(146,877,579)	\$(18,309 )
Issuance of common stock and warrants in public offering	1,670,000	1,670	5,277,270	-	5,278,940
Stock issuance costs associated with public offering	-	-	(809,277 )	-	(809,277 )
Issuance of common stock pursuant to Lincoln Park Equity Line	277,135	277	1,712,043	-	1,712,320
Cost associated with Lincoln Park Equity Line	-	-	(41,381 )	-	(41,381 )
Issuance of common stock in reverse stock split	1,525	1	-	-	1
Issuance of common stock to SciClone	352,942	353	2,999,647	-	3,000,000
Cashless exercise of warrants and reclassification of warrant liability to equity	33,978	34	892,826	-	892,860
Issuance of common stock to vendors	7,500	8	52,492	-	52,500
Share-based compensation expense	-	-	574,977	-	574,977
Net loss	-	-	-	(3,245,383 )	(3,245,383)
Balance, December 31, 2016	5,470,032	\$5,470	\$157,514,740	\$(150,122,962)	\$7,397,248

Adjusted to reflect the reverse stock split of one-for-ten effective October 7, 2016.

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



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

	2016	2015
Operating activities:		
Net loss	\$(3,245,383)	\$(7,831,230)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	89,928	247,458
Amortization of discount on debt	7,281	10,648
Share-based compensation	574,977	654,481
Gain on settlement of liability	(390,599 )	-
Issuance of common stock for services	52,500	232,212
Change in fair value of warrant liability	(1,541,241)	1,201,870
Change in operating assets and liabilities:		
Contracts and grants receivable	778,435	(1,190,445)
Prepaid expenses	109,836	(71,339 )
Accounts payable and accrued expenses	(1,475,128)	1,376,391
Accrued compensation	56,973	(16,354 )
Total adjustments	(1,737,038)	2,444,922
Net cash used in operating activities	(4,982,421)	(5,386,308)
Investing activities:		
Purchases of office furniture and equipment	(7,159 )	(22,098 )
Net cash used in investing activities	(7,159 )	(22,098 )
Financing activities:		
Proceeds from issuance of common stock and warrants from public offering	5,278,940	-
Stock issuance costs associated with public offering	(809,277 )	-
Proceeds from issuance of common stock pursuant to the equity lines	1,712,320	3,839,177
Stock issuance cost associated with equity lines	(41,381 )	(171,091 )
Repayment of notes payable	(300,000 )	-
Proceeds from issuance of common stock to SciClone	3,000,000	-
Proceeds from exercise of options and warrants	-	1,136,771
Net cash provided by financing activities	8,840,602	4,804,857
Net increase (decrease) in cash and cash equivalents	3,851,022	(603,549 )
Cash and cash equivalents at beginning of period	4,921,545	5,525,094
Cash and cash equivalents at end of period	\$8,772,567	\$4,921,545
Supplemental disclosure of non cash financing activities:		
Reclassification of warrant liability to additional paid-in capital	\$892,860	\$2,557,331
Notes payable issued in connection with Equity Purchase Agreement	\$-	\$282,071
Supplemental information:		
Cash paid for state income taxes	\$5,030	\$7,542



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

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Soligenix, Inc. and Subsidiaries  
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the “Company”) is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense.

The Company’s 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”), its first-in-class innate defense regulator (“IDR”) 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).

The Company’s Vaccines/BioDefense business segment includes active development programs for RiVax™, its ricin toxin vaccine candidate, OrbeShield®, a GI acute radiation syndrome (“GI ARS”) therapeutic candidate and SGX943, a melioidosis therapeutic candidate. The development of the vaccine program is currently supported by the 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”), the Company will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We had 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 NIAID. We will continue to pursue additional government funding support.

The Company generates revenues under government grants primarily from the National Institutes of Health (the “NIH”) and government contracts from BARDA and NIAID. The NIAID contract will be completed 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. We will continue to apply for additional government funding.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with the United States Food and Drug Administration (the U.S. "FDA") regulations, and other regulatory authorities, litigation, and product liability.

### Liquidity

In accordance with Accounting Standards Codification 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of December 31, 2016, the Company had an accumulated deficit of \$150,122,962. During the year ended December 31, 2016, the Company incurred a loss of \$3,245,383 and used \$4,982,421 of cash in operations. The Company expects to continue to generate losses in the foreseeable future. The Company's liquidity needs will be largely determined by the budgeted operational expenditures incurred in regards to the progression of its product candidates. The Company's plans to meet its liquidity needs primarily include its ability to control the timing and spending on its research and development programs and raising additional funds through potential partnership and/or financings. Based on the Company's approved operating budget, management believes that it will have sufficient capital to meet the anticipated cash needs for working capital and capital expenditures through at least March 31, 2018. Based on the Company's current rate of cash outflows, cash on hand, proceeds from government contract and grant programs, proceeds available from the equity line with Lincoln Park, LLC ("Lincoln Park") 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 following the issuance of this report.

As of December 31, 2016, the Company had cash and cash equivalents of \$8,772,567 as compared to \$4,921,545 as of December 31, 2015, representing an increase of \$3,851,022 or 78%. The increase in cash was primarily the result of net proceeds received from financing activities of \$8,840,602, primarily from a public offering of the Company's stock and the Company's stock purchase agreement with SciClone Pharmaceuticals, Inc. This was partially offset by cash used in operations of \$4,982,421. As of December 31, 2016, the Company had working capital of \$7,243,918 as compared to working capital of \$2,179,694, which excludes a non-cash warrant liability of \$2,434,101, as of December 31, 2015, representing an increase of \$5,064,224 or 232%. The increase in working capital was primarily the result of the increase in cash received from our financing activities.

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Management's business strategy can be outlined as follows:

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

Obtain agreement from the FDA on a pivotal Phase 3 protocol of SGX942 for the treatment of oral mucositis in head and neck cancer patients and initiate the trial;

Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease;

Continue development of RiVax™ in combination with the Company's ThermoVax® technology, to develop new heat stable vaccines in biodefense with NIAID 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 the Company's BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;

Pursue business development opportunities for the Company's pipeline programs, as well as explore merger/acquisition strategies; and

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

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

The Company has up to \$17.3 million in active government contract and grant funding still available to support its 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. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies;

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

The Company will pursue Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$530,143 in proceeds from the sale from NJ NOL in 2016, the Company expects to participate in the program during 2017 and beyond as long as the program is available;

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

The Company has \$10.3 million available from an equity facility expiring in March 2019; and

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

## Reverse Stock Split

On October 7, 2016, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of one-for-ten, whereby, once effective, every ten shares of its common stock was exchanged for one share of its common stock. The Company's common stock began trading on the OTCQB on a reverse split basis at the market opening on October 7, 2016. All share and per share data have been restated to reflect this reverse stock split.

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Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Operating Segments

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Contracts and Grants Receivable

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

Intangible Assets

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

The Company did not capitalize any patent related costs during the years ended December 31, 2016 or 2015.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the related asset or group of assets. No such write downs have occurred during the years ended December 31, 2016 and 2015.

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### Impairment of Long-Lived Assets

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

The Company did not record any impairment of long-lived assets for the years ended December 31, 2016 or 2015.

### Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on December 31, 2016. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

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

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

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation



methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

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

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, contracts and grants receivable, accounts payable, accrued expenses, notes payable and accrued compensation approximate their fair value based on the short-term maturity of these instruments. The Company recognizes all derivative financial instruments as assets or liabilities in the financial statements and measures them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with the Company's June 2013 registered public offering were accounted for as derivatives. See Note 5, *Warrant Liability*.

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### Revenue Recognition

The Company's 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 the Company incurs 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

The Company 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. The Company evaluated the provisions and determined the warrants issued in connection with the Company's June 2013 registered public offering contains provisions that protect holders from a decline in the issue price of the Company's 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 November 2016, the Company entered into amendments with the holders of those warrants pursuant to which the Company agreed to reduce the exercise price (after giving effect to the one-for-ten reverse stock split effective October 7, 2016) from \$5.10 per share to \$0.80 per share and permit those warrants to be exercised on a "cashless exercise" basis, and the Company eliminated the "down-round" provision of those warrants not immediately exercised. As a result of the amendments, the fair value of the warrant liability was remeasured for the year ended December 31, 2016 and the change in fair value was recognized in the statement of operations. The warrant liability related to the warrants not immediately exercised was then reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments. All other warrants that have been issued by the Company were indexed to the Company's stock and therefore are accounted for as equity instruments for 2016 and 2015.

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. These options have a ten year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position, the options will expire within three months, unless otherwise extended by the Board.

From time to time, the Company issues 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 and FASB ASC 505-50, *Equity-Based Payments to Non-Employees*, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The fair value is remeasured each reporting period until performance is complete.

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For the year ended December 31, 2016, the Company issued 66,875 stock options at a weighted average exercise price of \$5.30 per share. The fair value of options issued during the years ended December 31, 2016 and 2015 was estimated using the Black-Scholes option-pricing model and the following assumptions:

a dividend yield of 0%;  
an expected life of 4 years;  
volatility of 84% - 121% for 2016 and 121% - 141% for 2015;  
forfeitures at a rate of 12%; and  
risk-free interest rates ranging from 0.96% to 1.70% and 0.98% to 1.53% for 2016 and 2015, respectively.

The fair value of each option grant made during 2016 and 2015 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 December 31, 2016 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 2016 and 2015. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2016 and 2015.

## 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.

	For the Year Ended December 31, 2016	For the Year Ended December 31, 2015
Numerator:		
Net loss for basic earnings per share	\$ (3,245,383)	\$ (7,831,230 )
Less change in fair value of warrant liability	1,541,241	-
Net loss for diluted earnings per share	\$ (4,786,624)	\$ (7,831,230 )
Denominator:		
Weighted-average basic common shares outstanding	3,481,460	2,606,577
Assumed conversion of dilutive securities:		
Common stock purchase warrants	102,127	-
Denominator for diluted earnings per share – adjusted weighted-average shares	3,583,587	2,606,577
Basic net loss per share	(\$0.93 )	(\$3.00 )
Diluted net loss per share	(\$1.34 )	(\$3.00 )

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The following table summarizes potentially dilutive adjustments to the weighted average number of common shares which were excluded from the calculation because their effect would be anti-dilutive.

	For the Year Ended December 31, 2016	For the Year Ended December 31, 2015
Common stock purchase warrants	2,853,575	492,612
Stock options	330,605	276,861
Total	3,184,180	769,473

The weighted average exercise price of the Company's stock options and warrants outstanding at December 31, 2016 were \$17.07 and \$4.13 per share, respectively.

Use of Estimates and Assumptions

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

Recently Issued Accounting Pronouncements

In August 2014, FASB issued Accounting Standards Update ("ASU") No. 2014-15, "Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The amendments in this ASU are intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, this ASU provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard is effective for annual periods ending after December 15, 2016, and interim periods thereafter. The Company adopted the new standard effective December 31, 2016, and the adoption of the standard did not have an impact on the Company's consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases” (topic 842). The FASB issued this update to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The updated guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption of the update is permitted. The Company is evaluating the impact of the adoption of this update on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, and intends to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. It is effective for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. Early adoption is permitted. The Company is currently evaluating the impact of adoption of this update on our consolidated financial statements and related disclosures.

Table of Contents**Note 3. Intangible Assets**

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

	<b>Cost</b>	<b>Accumulated Amortization</b>	<b>Net Book Value</b>
December 31, 2016			
Licenses	\$462,234	\$ 361,044	\$101,190
Patents	1,893,185	1,867,747	25,438
Total	\$2,355,419	\$ 2,228,791	\$126,628
December 31, 2015			
Licenses	\$462,234	\$ 333,732	\$128,502
Patents	1,893,185	1,832,955	60,230
Total	\$2,355,419	\$ 2,166,687	\$188,732

Amortization expense was \$62,104 and \$221,217 in 2016 and 2015, respectively.

Based on the balance of licenses and patents at December 31, 2016, future annual amortization expense is expected to be as follows:

Year	Amortization Expense
2017	\$ 61,800
2018	\$ 37,300
2019	\$ 27,528

License fees and royalty payments are expensed annually as incurred, as the Company does not attribute any future benefits of such payments.

**Note 4. Accrued Expenses**

The following is a summary of the Company's accrued expenses:



For the Years Ended  
December 31,  
2016      2015

Clinical trial expenses	\$741,174	\$1,168,021
Executive bonuses	-	275,355
Other	64,944	67,168
Total	\$806,118	\$1,510,544

#### Note 5. Notes Payable

On July 29, 2015, the Company entered into equity purchase agreements (the “Equity Line Purchase Agreements”) and registration rights agreements with certain accredited institutional investors (see Note 7). In consideration for entering into the Equity Line Purchase Agreements, the Company issued to the investors promissory notes having an aggregate principal amount of \$300,000, which were recorded as stock issuance costs. The promissory notes had an issuance date present value of \$282,071 and were repaid on April 15, 2016. The promissory notes did not include terms for interest, therefore the interest was imputed at 9%. Total discount amortization of \$7,281 and \$10,648 was recorded as interest expense for the years ended December 31, 2016 and 2015, respectively. The discount was accreted over the term of the promissory notes using the effective interest rate method.

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## Note 6. Warrant Liability

On June 25, 2013, the Company consummated a public offering in which the Company issued shares of common stock, together with warrants to purchase shares of common stock. These warrants contained provisions that protected holders from a decline in the issue price of the Company's common stock (or "down-round" provision) and contained net settlement provisions. As a result, the Company accounted for these warrants as liabilities instead of equity instruments. Down-round provisions reduce the exercise or conversion price of a warrant if the Company issues equity shares for a price that is lower than the exercise or conversion price of the warrants. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of exercising the warrant by paying cash. The Company evaluates whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or the number of shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a "fixed for fixed" option. As a result of the Company's December 2014 registered public unit offering, the exercise price of warrants outstanding in connection with the public offering completed in June 2013 was adjusted to \$6.10 per share. As a result of the Company's December 2015 drawings on the Equity Line Purchase Agreements, the exercise price of warrants outstanding in connection with the public offering conducted in June 2013 was adjusted to \$5.10 per share. The Company recognized these warrants as liabilities at their fair value on the date of grant and remeasured them to fair value on each reporting date.

The Company recognized an initial warrant liability for the warrants issued in connection with the registered public offering completed in June 2013 totaling \$4,827,788, which was based on the June 25, 2013 closing price of a share of the Company's common stock as reported on OTC Markets of \$9.60. During November 2016, the Company entered into amendments with the holders of those warrants pursuant to which the Company agreed to reduce the exercise price (after giving effect to the one-for-ten reverse stock split effective October 7, 2016) from \$5.10 per share to \$0.80 per share and permit those warrants to be exercised on a "cashless exercise" basis, and the Company eliminated the "down round" provision of those warrants not immediately exercised. As a result of the amendments, the warrant liability was remeasured as of the date of the modification, which resulted in an approximate \$1,541,000 decrease in the carrying value of the warrant liability, which was recognized in the statement of operations for the year ended December 31, 2016. The warrant liability related to the warrants not immediately exercised was then reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments. Of the 303,694 shares of common stock that remained issuable upon the exercise of such warrants as of the amendment date, warrants to purchase a total of 42,444 shares were exercised on a cashless basis and as a result 33,978 shares of common stock were issued on November 9, 2016.

The assumptions used in the valuation of the warrants issued in the June 25, 2013 financing on November 9, 2016 using the Black Scholes model and for the year ended December 31, 2015 using the binomial method, respectively, were as follows:

November 9,	December 31,
2016	2015

Number of shares underlying the warrants	303,694		303,694	
Exercise price	\$ 0.80		\$ 5.10	
Volatility	93	%	98	%
Risk-free interest rate	0.81	%	1.19	%
Expected dividend yield	0	%	0	%
Expected warrant life (years)	1.63		2.48	
Stock price	\$ 3.65		\$ 11.30	

Recurring Level 3 Activity and Reconciliation

The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3).

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

	December 31, 2015	Decrease in Fair Value	Reclassification of warrant liability to equity in 2016	December 31, 2016
Warrant liability	\$ 2,434,101	\$(1,541,241)	\$( 892,860 )	\$ 0

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## Note 7. Income Taxes

The income tax benefit consisted of the following for the years ended December 31, 2016 and December 31, 2015:

	2016	2015
Federal	\$-	\$-
State	(530,143)	(488,933)
Income tax benefit	\$(530,143)	\$(488,933)

The significant components of the Company's deferred tax assets and liabilities at December 31, 2016 and 2015 are as follows:

	2016	2015
Net operating loss carry forwards	\$32,028,000	\$31,216,000
Orphan drug and research and development credit carry forwards	6,374,000	4,909,000
Equity based compensation	1,943,000	1,923,000
Intangibles	1,921,000	2,090,000
Total	42,266,000	40,138,000
Valuation allowance	(42,266,000)	(40,138,000)
Net deferred tax assets	\$-	\$-

The Company had gross NOLs at December 31, 2016 of approximately \$93,635,000 for federal tax purposes and approximately \$3,233,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which will begin to expire in 2018. In addition, the Company has \$6,374,000 of various tax credits which expire from 2018 to 2035. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carry forwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. During the years ended December 31, 2016 and 2015, in accordance with the State of New Jersey's Technology Business Tax Certificate Program, which allowed certain high technology and biotechnology companies to sell unused NOL carry forwards to other New Jersey-based corporate taxpayers, the Company sold New Jersey NOL carry forwards, resulting in the recognition of \$530,143 and \$488,933 of income tax benefit, net of transaction costs, respectively. There can be no assurance as to the continuation or magnitude of this program in the future.

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Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2016 and 2015 were as follows:

	2016	2015
Income tax loss at federal statutory rate	(34.0)%	(34.0)%
State tax benefits, plus sale of NJ NOLs, net of federal benefit	(7.9 )	(4.3 )
Permanent differences	10.3	15.0
Orphan drug and research and development credits	(38.8)	(16.3)
Change in valuation allowance	56.4	33.7
Income tax benefit	(14.0)%	(5.9 )%

Note 8. Shareholders' Deficiency

Preferred Stock

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

Common Stock

The following items represent transactions in the Company's common stock for the year ended December 31, 2016:

The Company issued Lincoln Park Capital Fund, LLC ("Lincoln Park") 277,135 shares of common stock pursuant to the equity line purchase agreement;

On May 31, 2016, the Company issued 5,000 shares of common stock to a vendor for partial consideration for services performed.

On August 29, 2016, the Company issued 2,500 shares of common stock to a vendor for partial consideration for services performed.

On September 9, 2016, the Company entered into a common stock purchase agreement with SciClone pursuant to which we sold 352,942 shares of the Company's common stock to SciClone for an aggregate price of \$3,000,000.

In November 2016, warrants to purchase a total of 42,444 shares were exercised on a cashless basis and as a result 33,978 shares of common stock were issued.

On December 16, 2016, 1,670,000 shares of the Company's common stock and warrants to purchase 2,087,500 shares of the Company's common stock at a combined offering price of \$3.16 were issued in a registered public offering. In addition, the underwriters partially exercised the over-allotment to purchase an additional 282,505 warrants. The warrants have a per share exercise price of \$3.95 and are exercisable immediately.

The following items represent transactions in the Company's common stock for the year ended December 31, 2015:

In February 2015, the Company issued 70,179 shares of common stock in connection with the exercise of stock warrants;

In March 2015, the Company issued 48,200 shares of common stock in connection with the exercise of stock warrants;

In March 2015, the Company issued 15,301 shares of common stock pursuant to the Lincoln Park facility;

In April 2015, the Company issued 35,679 shares of common stock in connection with the exercise of stock warrants;

In April 2015, the Company issued 812 shares of common stock in connection with the exercise of stock options;

In May 2015, the Company issued 7,636 shares of common stock pursuant to the Lincoln Park facility;

In June 2015, the Company issued 38,425 shares of common stock pursuant to the Lincoln Park facility;

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In June 2015, the Company issued 19,871 shares of common stock in connection with the exercise of stock warrants;  
In July 2015, the Company issued 714 shares of common stock in connection with the exercise of stock warrants;  
In September 2015, the Company issued 60,954 shares of common stock pursuant to an Equity Line Purchase Agreement;  
In September 2015, the Company issued 2,500 shares of common stock in connection with the exercise of stock options;  
In October 2015, the Company issued 15,184 shares of common stock pursuant to the Lincoln Park facility;  
In November 2015, the Company issued 7,589 shares of common stock pursuant to the Lincoln Park facility;  
In December 2015, the Company issued 393,623 shares of common stock pursuant to an Equity Line Purchase Agreement;  
In nine separate transactions, the Company issued 16,628 fully vested shares of common stock as partial consideration for services performed

Equity Line Purchase Agreement

On July 29, 2015, the Company entered into the Equity Line Purchase Agreements and registration rights agreements with accredited institutional investors, Kodiak Capital Group, LLC (“Kodiak Capital”), Kingsbrook Opportunities Master Fund LP (“Kingsbrook”) and River North Equity, LLC (“River North” and, together with Kodiak Capital and Kingsbrook, the “Investors”). Under the Equity Line Purchase Agreements, the Investors agreed to purchase from the Company up to an aggregate of \$10 million worth of shares of common stock, from time to time. In accordance with the registration rights agreements, the Company has filed with the U.S. Securities and Exchange Commission (“SEC”) a registration statement to register for resale under the Securities Act of 1933, as amended, the shares of common stock that may be issued to the Investors under the Equity Line Purchase Agreements.

From the date that the SEC declared the registration statement effective in August 2015, the Company had the right to sell up to \$5 million, \$4 million and \$1 million worth of shares of common stock to Kodiak Capital, Kingsbrook and River North, respectively. The purchase price of the shares was equal to eighty percent (80%) of the lowest daily volume weighted average price of the common stock for any trading day during the five consecutive trading days immediately following the date of the Company’s notice to the Investors requesting the purchase.

In consideration for entering into the Equity Line Purchase Agreements, the Company issued to each of the Investors a promissory note having a principal amount equal to 3% of the total amount committed by such Investor. The principal amount due under the promissory notes did not accrue interest and was payable by April 15, 2016. The promissory notes were repaid on April 15, 2016 (see Note 4).

The initial drawdown under the Equity Line Purchase Agreements was \$500,000 offset by issuance cost of \$453,162, which is included in the Consolidated Statements of Changes in Shareholders’ Deficiency for the year ended December 31, 2015. Issuance costs include professional fees, 3% commitment fee (promissory notes payable by April 15, 2016) and SEC filing fees.



In December 2015, a second drawdown was made, whereby under the Equity Line Purchase Agreements, the Company issued 393,624 shares of common stock receiving proceeds of \$2,000,000.

On March 7, 2016, in accordance with the terms of the Equity Line Purchase Agreements, the Company exercised its right to terminate the Purchase Agreements upon written notice to the Investors. The Company did not incur any penalties as a result of this termination.

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Equity Line

In November 2013, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC (“Lincoln Park”). The Lincoln Park equity facility allowed the Company to require Lincoln Park to purchase up to \$10.6 million of our common stock over a 36-month period depending on certain conditions. During the year ended December 31, 2015, the Company sold 82,500 shares of common stock and issued 1,635 commitment shares to Lincoln Park receiving net proceeds of \$1,339,177. During the year ended December 31, 2016, there were no sales of common stock under the Lincoln Park 2013 equity facility. The 2013 Lincoln Park equity facility expired in November 2016 in accordance with the terms of the agreement.

In March 2016, the Company entered into a common stock purchase agreement with Lincoln Park. The 2016 Lincoln Park equity facility allows the Company to require Lincoln Park to purchase up to 10,000 shares (“Regular Purchase”) of the Company’s common stock every two business days, up to an aggregate of \$12.0 million over approximately a 36-month period with such amounts increasing as the quoted stock price increases. The Regular Purchase may be increased up to 15,000 shares of common stock if the closing price of the common shares is not below \$10.00, up to 20,000 shares of common stock if the closing price of the common shares is not below \$15.00 and up to 25,000 shares of common stock if the closing price of the common shares is not below \$20.00. The purchase price for the Regular Purchase shall be equal to the lesser of (i) the lowest sale price of the common shares during the purchase date, or (ii) the average of the three lowest closing sale prices of the common shares during the twelve business days prior to the purchase date. Each Regular Purchase shall not exceed \$750,000. Furthermore, for each purchase by Lincoln Park, additional commitment shares in commensurate amounts up to a total of 50,000 shares will be issued based upon the relative proportion of the aggregate amount of \$12.0 million. In addition to the Regular Purchase and provided that the closing price of the common shares is not below \$7.50 on the purchase date, the Company in its sole discretion may direct Lincoln Park on each purchase date to purchase on the next stock trading day (Accelerated Purchase Date”) additional shares of Company stock up to the lesser of (i) three times the number of shares purchased following a Regular Purchase or (ii) 30% of the trading volume of shares traded on the Accelerated Purchase Date at a price equal to the lesser of the closing sale price on the Accelerated Purchase Date or 95% of the Accelerated Purchase Date’s volume weighted average price.

Upon entering into the agreement, the Company issued 10,000 shares of common stock as consideration for its commitment to purchase shares of the Company’s common stock under the purchase agreement. The value of these shares on the date granted was \$81,000, which was accounted for as a stock issuance cost.

During the year ended December 31, 2016, the Company sold 260,000 shares of common stock and issued 7,135 commitment shares and received proceeds of \$1,712,320. The value of commitment shares on the date granted was \$47,244 which was accounted for as a stock issuance cost.

Note 9. Stock Option Plans and Warrants to Purchase Common Stock

Stock Option Plans

The Amended and Restated 2005 Equity Incentive Plan was replaced by the 2015 Equity Incentive Plan (“2015 Plan”), approved in June 2015, with 300,000 shares available under the 2015 Plan, and is divided into four separate equity programs:

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

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

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

The 2005 Plan expired in 2015 and thus no securities remain available for future issuance under that plan.

The table below accounts only for transactions occurring as part of the 2015 Plan.

Shares available for grant at January 1, 2016	252,300
Options granted	(66,875 )
Options forfeited	344
Shares available for grant at December 31, 2016	185,679

The total option activity for the amended 2005 Plan and the 2015 Plan for the years ended December 31, 2016 and 2015 was as follows:

	Options	Weighted Average Options Exercise Price
Balance outstanding at December 31, 2014	248,828	\$ 24.00
Granted	60,534	11.90
Exercised	(3,312 )	5.80
Forfeited	(29,189 )	31.30
Balance outstanding at December 31, 2015	276,861	\$ 21.30
Granted	66,875	5.30
Increase post reverse stock split	1,851	17.07
Exercised	-	-
Forfeited	(14,982 )	48.52

Balance outstanding at December 31, 2016 330,605 \$ 17.07

As of December 31, 2016, there were 258,996 options exercisable with a weighted average exercise price of \$19.58, a weighted average remaining contractual term of 7.43 years and an intrinsic value of \$0. The intrinsic value of options exercised during the year ended December 31, 2015 was \$18,181. As of December 31, 2016, there were 330,605 options outstanding and expected to vest with a weighted average exercise price of \$17.07, weighted average remaining term of 5.82 years and an intrinsic value of \$0. The aggregate intrinsic value represents the total pre-tax intrinsic value (the difference between the closing price of our common stock on the last trading day on December 31, 2016 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2016. This amount changes based on the fair market value of our common stock.

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The Company awarded 66,875 and 60,534 stock options to new employees and existing Board members during the years ended December 31, 2016 and 2015, respectively, which had a weighted average grant date fair value per share of \$3.90 and \$9.48, respectively. The weighted-average exercise price, by price range, for outstanding options to purchase common stock at December 31, 2016 was:

<b>Price Range</b>	<b>Weighted Average Remaining Contractual Life in Years</b>	<b>Outstanding Options</b>	<b>Exercisable Options</b>
\$2.25-\$19.50	6.14	235,475	165,144
\$20.00-\$41.00	6.36	63,080	61,802
\$46.40-\$94.00	2.43	32,050	32,050
Total	5.82	330,605	258,996

The Company's share-based compensation expense for the years ended December 31, 2016 and 2015 was recognized as follows:

Share-based compensation	2016	2015
Research and development	\$230,573	\$260,204
General and administrative	344,404	394,277
Total	\$574,977	\$654,481

At December 31, 2016, the total compensation cost for stock options not yet recognized was approximately \$407,520 and will be expensed over the next three years.

Warrants to Purchase Common Stock

As described in Note 5. Warrant Liability, during November 2016, the Company entered into amendments with the holders of the price protected warrants issued in the June 2013 registered public offering eliminating the "down round" provision and permitting those warrants to be exercised on a "cashless exercise" basis. Of the 303,694 shares of common stock that remained issuable on the date of the amendments upon the exercise of such warrants, warrants to purchase a total of 42,444 shares were exercised on a cashless basis on November 9, 2016. The fair value of the warrant liability of \$892,860 related to the remaining 261,250 warrants outstanding after the amendment and exercises was reclassified to equity as the amended terms of the warrants qualified them to be accounted for as equity instruments.

On December 16, 2016, 1,670,000 shares of our common stock and warrants to purchase 2,087,500 shares of the Company's common stock at a combined offering price of \$3.16 were issued in a registered public offering. In addition, the underwriters partially exercised the over-allotment to purchase an additional 282,505 warrants. Commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of \$3.95 per share, prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. The warrants are traded on the Nasdaq Capital Market under the symbol "SNGXW".

In connection with the registered public offering, a warrant to purchase 33,400 shares of the Company's common stock was issued to the representative of the underwriters of the offering. The warrant is exercisable at \$3.95 per share of common stock underlying the warrant for a four-year period commencing one year from the effective date of the offering.

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Warrant activity for the years ended December 31, 2016 and 2015 was as follows:

	Warrants	Weighted Average Warrant Exercise Price
Balance at December 31, 2014	726,950	\$ 11.50
Exercised	(174,643 )	6.40
Expired	(59,693 )	55.90
Balance at December 31, 2015	492,614	\$ 7.40
Granted	2,403,405	3.95
Exercised	(42,444 )	0.80
Balance at December 31, 2016	2,853,575	\$ 4.13

The weighted-average remaining life, by grant date, for outstanding warrants at December 31, 2016 was:

Grant Date	Exercise Price	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
11/15/2012	\$ 6.80	0.87	5,000	5,000
12/20/2012	5.30	0.97	44,488	44,488
12/20/2012	5.80	0.97	28,000	28,000
6/25/2013	0.80	1.48	261,250	261,250
12/5/2013	20.50	1.93	500	500
12/24/2014	14.80	2.98	110,932	110,932
12/16/2016	\$ 3.95	4.96	2,403,405	2,370,005
	Total	4.45	2,853,575	2,820,175

## Note 10. Concentrations

At December 31, 2016 and 2015, the Company had deposits in major financial institutions that exceeded the amount under protection by the Securities Investor Protection Corporation (“SIPC”). Currently, the Company is covered up to \$1,000,000 by the SIPC and at times maintains cash balances in excess of the SIPC coverage.



Note 11. Commitments and Contingencies

The Company has commitments of approximately \$500,000 at December 31, 2016 for several licensing agreements with consultants and universities. Additionally, the Company has 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 December 31, 2016, no milestones or royalty payments have been paid or accrued.

In December 2014, the Company 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 will increase to approximately \$12,460 per month, or approximately \$21.13 per square foot for the remainder of the lease. Rent expense was \$148,336 and \$142,935 for 2016 and 2015, respectively.

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On September 3, 2014, the Company entered into an asset purchase agreement with Hy Biopharma, Inc. (“Hy Biopharma”) pursuant to which the Company 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, the Company paid \$275,000 in cash and issued 184,912 shares of common stock with a fair value based on the Company’s stock price on the date of grant 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 the Company’s 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, the Company will be required to make additional payments of up to \$10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company provided they do not exceed 19.9% ownership of the Company’s outstanding stock. As of December 31, 2016, no milestone or royalty payments have been paid or accrued.

In February 2007, the Company’s Board of Directors authorized the issuance of 5,000 shares of the Company’s common stock to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party. Dr. Schaber’s amended employment agreement includes the Company’s obligation to issue such shares if such event occurs.

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

<b>Year</b>	<b>Research and Development</b>	<b>Property and Other Leases</b>	<b>Total</b>
2017	\$ 100,000	\$ 151,000	\$ 251,000
2018	100,000	52,000	152,000
2019	100,000	-	100,000
2020	100,000	-	100,000
2021	100,000	-	100,000
Total	\$ 500,000	\$ 203,000	\$ 703,000

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## Note 12. Operating Segments

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

	<b>For the Years Ended</b>	
	<b>December 31,</b>	
	<b>2016</b>	<b>2015</b>
Revenues		
Vaccines/BioDefense	<b>\$10,448,794</b>	\$8,754,418
BioTherapeutics	-	13,972
Total	<b>\$10,448,794</b>	\$8,768,390
Income (Loss) from Operations		
Vaccines/BioDefense	<b>\$1,563,884</b>	\$1,263,709
BioTherapeutics	<b>(3,399,933)</b>	(4,487,988)
Corporate	<b>(3,873,533)</b>	(3,885,997)
Total	<b>\$(5,709,582)</b>	\$(7,110,276)
Amortization and Depreciation Expense		
Vaccines/BioDefense	<b>\$40,186</b>	\$39,925
BioTherapeutics	<b>41,395</b>	199,661
Corporate	<b>8,347</b>	7,872
Total	<b>\$89,928</b>	\$247,458
Other Income (Expense), Net		
Corporate	<b>\$1,934,056</b>	\$(1,209,887)
Share-Based Compensation		
Vaccines/BioDefense	<b>\$99,410</b>	\$111,960
BioTherapeutics	<b>131,163</b>	148,244
Corporate	<b>344,404</b>	394,277
Total	<b>\$574,977</b>	\$654,481

**As of December 31,**  
2016                      2015

Identifiable Assets		
Vaccines/BioDefense	<b>\$1,297,986</b>	\$2,123,676
BioTherapeutics	<b>49,422</b>	76,183
Corporate	<b>8,919,698</b>	5,187,263
Total	<b>\$10,267,105</b>	\$7,387,122

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of  
Soligenix, Inc.

We have audited the accompanying consolidated balance sheets of Soligenix, Inc. and Subsidiaries (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations, shareholders’ equity (deficiency), and cash flows for each of the years then ended. The financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Soligenix, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Philadelphia, PA  
March 27, 2017

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**SOLIGENIX, INC.**

**982,000 SHARES OF COMMON STOCK**

**PROSPECTUS**

**November 30, 2017**