SOLIGENIX, INC.
Form S-1/A
November 21, 2016
As filed with the Securities and Exchange Commission on November 21, 2016.

Registration No. 333-214038

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

AMENDMENT NO. 3 TO
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

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

Soligenix, Inc.
29 Emmons Drive, Suite C-10
Princeton, New Jersey 08540
(609) 538-8200

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
Soligenix, Inc.
29 Emmons Drive, Suite C-10
Princeton, New Jersey 08540
(609) 538-8200

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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with copies to:

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[1]	Amount of registration fee[1][3]	
Common Stock, $0.001 par value[2][3]			
Common Stock Purchase Warrants			
Shares of Common Stock, $0.001 par value per share, underlying Common Stock Purchase Warrants[2][3]			
Representative's Warrants[5]			
Shares of Common Stock underlying Representative's Warrants[2][3][6]			
Total	$13,535,230.89	$1,568.75	(6)

(1) Estimated solely for purposes of calculating the registration fee according to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Includes shares of common stock the underwriters have the option to purchase to cover over-allotments, if any. This registration statement also covers the preferred stock purchase rights issuable in accordance with the Rights Agreement, dated June 22, 2007, between the Registrant and American Stock Transfer & Trust Company, as Rights Agent, which are presently attached to and trade with the Registrant's common stock.

(3) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(4) No fee pursuant to Rule 457(g) under the Securities Act.

(5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act.

(6) Previously paid.

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

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the Registration Statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED NOVEMBER 21, 2016

Up to $6 Million of Shares of Common Stock plus

Warrants to Purchase Shares of Common Stock

We are offering up to $6 million of shares of our common stock plus warrants to purchase shares of our common stock pursuant to this prospectus (and the shares of our common stock that are issuable from time to time upon exercise of the warrants). The warrants will have a per share exercise price of 125% of the public offering price of the common stock. Each warrant will have the right to purchase three-quarters of one share of our common stock. The shares of our common stock and the warrants will be separately issued. The warrants are exercisable immediately and will expire five years from the date of issuance. On October 7, 2016, we effected a one-for-ten reverse stock split of our issued and outstanding common stock.

Our common stock is quoted on the OTCQB market under the symbol “SNGX.” We have applied to list our common stock and warrants on The NASDAQ Capital Market under the symbols “SNGX” and “SNGXW,” respectively. No assurance can be given that our application will be approved. On November 17, 2016, the last quoted sale price for our common stock on the OTCQB was $3.14 per share, adjusted for the one-for-ten reverse stock split we effected on October 7, 2016.

Our business and an investment in our securities involves a high degree of risk. See “Risk Factors” beginning on page 8 of this prospectus for a discussion of information that you should consider before investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Per Warrant	Total
Public offering price	$	$	$
Discounts and commissions to underwriters(1)	$	$	$
Offering proceeds to us, before expenses	$	$	$

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(1) The underwriters will receive compensation in addition to the underwriting discount. See “Underwriting” beginning on page 77 of this prospectus for a description of compensation payable to the underwriters.

We have granted a 45-day option to the representative of the underwriters to purchase up to 286,624 additional shares of common stock and/or warrants to purchase 214,968 shares of common stock from us solely to cover over-allotments, if any (based on the closing price of $3.14 on November 17, 2016).

The underwriters expect to deliver the shares and warrants against payment therefor on or about , 2016.

Sole Book-Running Manager

Aegis Capital Corp

Co-Manager

Maxim Group LLC

, 2016

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. You should read this entire prospectus carefully, especially the "Risk Factors" section of this prospectus and the financial statements and related notes appearing at the end of this prospectus 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 light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We plan to use the funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from NIAID to advance the development of OrbeShield® for the treatment of GI ARS.

An outline for 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 to collect the long-term follow-up safety data from the SGX942 Phase 2 proof-of-concept study for the treatment of oral mucositis in head and neck cancer patients and publish the findings from this study;

- Obtain agreement from the United States Food and Drug Administration (the "FDA") on a pivotal Phase 2b/3 protocol 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;

- 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 under the BARDA contract and with NIAID 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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Our Product Candidates in Development

The following tables summarize our product candidates under development:

BioTherapeutic Product Candidates Soligenix Product Candidate	Therapeutic Indication	Stage of Development
SGX301	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 clinical trial initiated in the second half of 2015, with data expected in the second half of 2017
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial initiated in the second half of 2013, with positive preliminary results reported in the second half of 2015 and long-term data expected in the second half of 2016; seek to obtain FDA agreement on the Phase 2b/3 protocol in the first half of 2017
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed in June 2013, efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety profile demonstrated; Phase 3 clinical trial planned for the first half of 2017, with data expected in the second half of 2018
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety profile and preliminary efficacy demonstrated

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

BioDefense Product Candidates** Soligenix Product Candidate	Indication	Stage of Development
RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1b trial complete, safety and neutralizing antibodies for protection demonstrated; Phase 1/2 trial planned for the second half of 2017

OrbeShield®	Therapeutic against GI ARS	Pre-clinical
SGX943	Melioidosis	Pre-clinical

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

Corporate Information

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

The Offering

Securities offered by us	Up to $6 million of shares of our common stock and warrants to purchase shares of common stock.
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to $900,000 of additional shares of our common stock from us at the public offering price less underwriting discounts and commissions and/or additional warrants to purchase shares of our common stock.
Representative's warrants	We will issue to Aegis Capital Corp. ("Aegis"), the representative of the underwriters, upon closing of this offering, compensation warrants entitling Aegis or its designees to purchase 2.0% of the aggregate number of the shares of common stock that we issue in this offering (excluding any shares issued upon exercise of the underwriters' over-allotment option). The representative's warrants will be exercisable for no more than 5 years from the effective date of this offering and may be exercised commencing 12 months after the date of effectiveness of the registration statement of which this prospectus forms a part. The representative's warrants may be exercised on a cashless basis.
Common stock outstanding after this offering	5,710,861 shares of common stock, assuming a public offering price of $3.14 per share, which is the last reported sale price of our common stock on the OTCQB on November 17, 2016 (7,143,983 if the warrants offered hereby are exercised in full). If the underwriters' over-allotment option is exercised in full, the total number of shares of common stock outstanding immediately after this offering would be 5,997,485 (7,645,575 if the warrants offered hereby are exercised in full). This prospectus also includes the shares of our common stock issuable upon exercise of the warrants.
Description of the warrants	The warrants will have a per share exercise price equal to 125% of public offering price of the common stock. The warrants are exercisable immediately and expire five years from the date of issuance.
Use of proceeds	We estimate that the net proceeds from our sale of our securities in this offering will be approximately $5.2 million, or approximately $6.1 million if the underwriters exercise their over-allotment option in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds received from this offering to fund our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL and our pivotal Phase 2b/3 protocol of SGX942 for the treatment of oral mucositis in head and neck cancer patients, as well as for general working capital purposes. See "Use of Proceeds" on page 30.
Risk Factors	See the section entitled "Risk Factors" beginning on page 8 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.
OTC Markets (OTCQB) symbol	SNGX

Proposed symbols and listing	We have applied to list our common stock and warrants on The NASDAQ Capital Market under the symbols “SNGX” and “SNGXW,” respectively. We estimate that we will need to receive minimum gross proceeds of $6.0 million in order to satisfy The NASDAQ Capital Market’s initial shareholders’ equity listing requirement.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 3,800,032 shares of common stock outstanding as of November 17, 2016, and assumes the issuance and sale of $6 million of shares of our common stock in this offering at an assumed public offering price of $3.14 per share, which was the last reported sale price of our common stock on the OTCQB on November 17, 2016.

Unless we indicate otherwise, all information in this prospectus:

- reflects a one-for-ten reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on October 7, 2016 and the corresponding adjustment of all common stock prices per share and stock option and warrant exercise prices per share;

- is based on 3,800,032 shares of common stock issued and outstanding as of November 17, 2016;

- assumes no exercise by the underwriters of their option to purchase up to an additional 286,624 shares of common stock and/or warrants to purchase 214,968 shares of common stock to cover over-allotments, if any (based on the closing price of $3.14 on November 17, 2016);

- excludes 38,217 shares of our common stock underlying warrants to be issued to the representative of the underwriters in connection with this offering;

- excludes 1,433,122 shares of our common stock underlying warrants to be issued in this offering;

- excludes 261,250 shares of common stock issuable upon conversion of outstanding warrants to purchase shares of our common stock exercisable at $0.80 per share as of November 17, 2016;

- excludes 188,920 shares of our common stock issuable upon exercise of other outstanding warrants at a weighted average exercise price of $11.03 per share as of November 17, 2016; and

- excludes 299,752 shares of our common stock issuable upon exercise of outstanding stock options under our equity compensation plans at a weighted average exercise price of $18.20 per share as of November 17, 2016.

SUMMARY FINANCIAL DATA

The following table sets forth our summary statement of operations data for the fiscal years ended December 31, 2015 and 2014 derived from our audited financial statements and related notes included elsewhere in this prospectus. The summary financial data for the nine months ended September 30, 2016 and 2015, and as of September 30, 2016, are derived from our unaudited financial statements appearing elsewhere in this prospectus and are not indicative of results to be expected for the full year. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. The results indicated below are not necessarily indicative of our future performance. You should read this information together with the sections entitled "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Nine Months Ended September 30,		Year Ended December 31,	
	2016	2015	2015	2014
Revenues				
Contract revenue	$ 8,750,291	$ 5,668,746	$ 8,641,348	$ 5,545,468
Grant revenue	—	127,042	127,042	1,497,548
Total revenues	8,750,291	5,795,788	8,768,390	7,043,016
Cost of revenues	(7,204,920)	(4,394,915)	(6,882,204)	(5,313,855)
Gross profit	1,545,371	1,400,873	1,886,186	1,729,161
Operating expenses:				
Research and development	3,433,595	3,731,813	5,399,839	5,086,535
Acquired in-process research and development	—	—	—	4,000,000
General and administrative	2,526,255	2,531,744	3,596,623	3,403,975
Total operating expenses	5,959,850	6,263,557	8,996,462	12,490,510
Loss from operations	(4,414,479)	(4,862,684)	(7,110,276)	(10,761,349)
Other income (expense):				
Change in fair value of warrant liability	1,109,192	(907,368)	(1,201,870)	3,436,195
Other income	390,599	—	—	—
Interest income (expense), net	(736)	(2,616)	(8,017)	1,310
Total other income (expense)	1,499,055	(909,984)	(1,209,887)	3,437,505
Net loss	$ (2,915,424)	$ (5,772,668)	$ (7,831,230)	$ (6,706,972)
Basic net loss per share[1]	$ (0.90)	$ (2.26)	$ (3.00)	$ (3.25)
Diluted net loss per share[1]	$ (1.20)	$ (2.26)	$ (3.00)	$ (4.30)
Basic weighted average common shares outstanding[1]	3,245,653	2,553,930	2,606,577	2,063,842
Diluted weighted average common shares outstanding[1]	3,347,837	2,553,930	2,606,577	2,358,494

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

	As of September 30, 2016	
	Actual	Pro Forma, As Adjusted[(1)]
Balance Sheet Data:		
Cash and cash equivalents	$ 5,655,200	$ 10,946,738
Total assets	$ 7,753,804	$ 13,045,342
Total liabilities	$ 5,583,373	$ 4,258,464
Total shareholders' equity	$ 2,170,431	$ 8,786,878

(1) Pro forma, as adjusted amounts give effect to (i) the issuance of 44,283 shares of common stock for which we received $73,210 from October 1, 2016 through and immediately prior to the date of this prospectus, (ii) the remeasurement of the $1,324,909 warrant liability as of the date of the amendment to the terms of the warrants issued in the 2013 public offering, which resulted in an approximate $430,000 decrease in the carrying value of the warrant liability which was recognized in the statement of operations on the date of the modification, and the reclassification of the warrant liability to equity and (iii) the sale of the shares in this offering at the assumed public offering price of $3.14 per share, which is based on the closing price of our common stock on November 17, 2016 and warrants at the public offering price of $0.01 per warrant, and after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

Recent Developments

License Agreement and Stock Sale

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 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.

Reverse Stock Split

Pursuant to the authority granted to our Board of Directors by our stockholders at the 2016 Annual Meeting of Stockholders, our Board of Directors authorized a one-for-ten reverse stock split of our common stock for all stockholders of record as of the close of business on October 6, 2016 and proportionately reduced the number of shares of our common stock authorized for issuance. As a result of the reverse split, the total number of outstanding shares of common stock was reduced to approximately 3.8 million shares and the conversion ratio for all instruments convertible into or exercisable for shares of common stock, including stock options and warrants, was proportionately adjusted. In addition, our total number of authorized shares of common stock was reduced to 10.0 million shares.

The reverse split was implemented in preparation for the proposed up-listing of our common stock to The NASDAQ Capital Market ("NASDAQ"). The NASDAQ listing is expected to facilitate more liquidity in the stock as well as

enable broader access to the investment community, many participants of which are unable to buy stock listed on the bulletin board.

The reverse split was intended to fulfill the stock price requirements for listing on NASDAQ since the requirements include, among other things, that our common stock must maintain a minimum closing price per share of $3.00 or higher for five consecutive trading days immediately prior to up-listing. Additionally, we estimate that we will need to receive minimum gross proceeds of $6.0 million in order to satisfy NASDAQ's initial shareholders' equity listing requirement. Before any listing of our common stock on NASDAQ could occur, NASDAQ will need to approve our application for listing. We believe that we will meet all of the listing requirements for listing our common stock on NASDAQ; however, there is no assurance that our application will be approved.

Our common stock began trading on the OTCQB on a reverse split basis on October 7, 2016. All share and per share data set forth herein have been adjusted to reflect this reverse stock split.

Warrant Amendment

On June 25, 2013, we consummated a public offering in which we 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 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. As of September 30, 2016, 303,694 shares of common stock remained issuable upon the exercise of such warrants, for which we recognized a non-cash liability of $1,324,909. 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 $430,000 decrease in the carrying value of the warrant liability, which was recognized in the statement of operations on the date of the modification. The warrant liability 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 42,444 shares were exercised on a cashless basis and as a result 33,978 shares of common stock were issued through November 9, 2016.

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, 2016, had an accumulated deficit of approximately $149.8 million. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of September 30, 2016, we had approximately $5.7 million in cash and cash equivalents available. Based on our projected budgetary needs, funding from existing contracts and grants over the next two years and sales to the purchasers under our existing equity lines, we expect to be able to maintain the current level of our operations for at least the next 12 months.

We have sufficient funds through our existing biodefense grant facilities from the NIAID, a division of the National Institutes of Health (the “NIH”), and BARDA to finance our biodefense projects for the next six years. In September 2014, we entered into a contract with the NIH for the development of RiVax™ to protect against exposure to ricin toxin that would provide up to $24.7 million of funding in the aggregate if options to extend the contract are exercised by the NIH. In September 2013, we entered into contracts with the NIH and BARDA for the development of OrbeShield® that would provide up to $33.7 million of funding in the aggregate if options to extend the contracts are exercised by BARDA and the NIH. In September 2009, we received a NIAID grant for approximately $9.4 million for the development of our biodefense programs. In July 2012, we received an additional Small Business Innovation and Research (“SBIR”) grant from NIAID for $600,000 and in February 2014, we were awarded a one-year NIAID SBIR grant award of approximately $300,000 to further evaluate SGX943 as a treatment for melioidosis. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component associated with our existing contracts and grants will fund some fixed costs for direct employees working on these contracts and grants as well as other administrative costs. As of September 30, 2016, we had approximately $35.1 million in awarded contract funding, assuming all options are exercised.

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, 2016, we have expended approximately $70.3 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least $12 million over the next 12 months in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements of which approximately $6.2 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.

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.

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 preclinical 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.

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

To date, we have no approved product on the market and have not generated any significant product revenues. We have funded our operations primarily from sales of our securities and from government grants. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or

with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential or successfully obtain government procurement or stockpiling agreements. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

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

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

There may be unforeseen challenges in developing our biodefense products.

For development of biodefense vaccines and therapeutics, the FDA has instituted policies that are expected to result in accelerated approval. This includes approval for commercial use using the results of animal efficacy trials, rather than efficacy trials in humans, referred to as the Animal Rule. However, we will still have to establish that the vaccines we are developing are safe in humans at doses that are correlated with the beneficial effect in animals. Such clinical trials will also have to be completed in distinct populations that are subject to the countermeasures; for instance, the very young and the very old, and in pregnant women, if the countermeasure is to be licensed for civilian use. Other agencies will have an influence over the risk benefit scenarios for deploying the countermeasures and in establishing the number of doses utilized in the Strategic National Stockpile. We may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these correlates are difficult to establish and are often unclear. Invocation of the Animal Rule may raise issues of confidence in the model systems even if the models have been validated. For many of the biological threats, the animal models are not available and we may have to develop the animal models, a time-consuming research effort. There are few historical precedents, or recent precedents, for the development of new countermeasure for bioterrorism agents. Despite the Animal Rule, the FDA may require large clinical trials to establish safety and immunogenicity before licensure and it may require safety and immunogenicity trials in additional populations. Approval of biodefense products may be subject to post-marketing studies, and could be restricted in use in only certain populations. The government’s biodefense priorities can change, which could adversely affect the commercial opportunity for the products we are developing. Further, other countries have not, at this time, established criteria for review and approval of these types of products outside their normal review process, i.e., there is no Animal Rule equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

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

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

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense

division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our receipt of government funding is also dependent on our ability to adhere to the terms and provisions of the original grant documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for grants we have been awarded. The loss of government funds could have a material adverse effect on our ability to progress our biodefense business.

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.

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.

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.

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;
- 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.

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. 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.

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.

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.

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 19 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, 2015, we sold New Jersey NOL carryforwards, resulting in the recognition of $488,933 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.

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.

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 and this Offering

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 and warrants 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;
- economic and other external factors; and
- 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;
- general market conditions.

Since January 1, 2015, the closing stock price (split adjusted) of our common stock has fluctuated between a high of $29.50 per share to a low of $3.11 per share. On November 17, 2016, the last quoted sale price of our common stock as reported on the OTCQB was $3.14 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock by the Company, as well as potential sale of common stock by the holders of warrants and options, could have an adverse effect on the market price of our shares.

A limited public trading market may cause volatility in the price of our common stock and warrants.

Our common stock trades on the OTCQB securities market under the symbol “SNGX.” The OTCQB is a decentralized market regulated by the Financial Industry Regulatory Authority in which securities are traded via an electronic quotation system that serves more than 3,000 companies, but provides significantly less liquidity than national market

systems such as the NYSE MKT. On the OTCQB, securities are traded by a network of brokers or dealers who carry inventories of securities to facilitate the buy and sell orders of investors, rather than providing the order matchmaking service seen in specialist exchanges. OTCQB securities include national, regional, and foreign equity issues. Companies traded on the OTCQB must be current in their reports filed with the Securities and Exchange Commission (the "SEC") and other regulatory authorities.

Since our common stock is not listed on a national exchange or market, the trading market for our common stock may become illiquid, and even if listed on a national exchange or market, it may be illiquid. If the price of our common stock falls, our common stock may become subject to the penny stock rules of the SEC, which generally

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

Although one reason we implemented a reverse stock split was to increase the price per share of our common stock such that it would not be subject to the "penny stock" rules, and our stock closed at $3.14 per share on November 17, 2016, no assurance can be given that the per share price of our common stock will maintain such levels such that our stock will not be subject to these rules in the future.

Holders of the warrants will have no voting rights as common stockholders until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of the warrants, you will have no rights with respect to our common stock issuable upon exercise of the warrants. Upon exercise of your warrants, you will be entitled to exercise all the voting rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Significant holders or beneficial holders of our common stock may not be permitted to exercise warrants that they hold.

The warrant agency agreement governing the warrants being offered hereby will prohibit a holder from exercising its warrants if doing so would result in such holder (together with such holder's affiliates and any other persons acting as a group together with such holder or any of such holder's affiliates) beneficially owning more than 4.99% of our common stock outstanding immediately after giving effect to the exercise. As a result, you may not be able to exercise your warrants for shares of our common stock at a time when it would be financially beneficial for you to do so. In such circumstance you could seek to sell your warrants to realize value, but you may be unable to do so.

The warrants are speculative in nature.

The warrants offered hereby do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, 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 125% of the public offering price of the common stock, prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

The warrants may not have any value.

Each warrant will have an exercise price of 125% of the public offering price of the common stock and will expire on the fifth anniversary of the original issuance date. In the event our common stock price does not exceed the exercise

price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

Investors will experience immediate and substantial dilution as a result of this offering and may suffer substantial dilution related to issued stock warrants and options.

Investors will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to 1,910,829 shares of common stock and warrants to purchase up to an aggregate of 1,433,122 shares of common stock offered in this offering at an assumed public offering price of $3.14 per share (based upon the closing price on November 17, 2016) and $0.01 per warrant, and after deducting the underwriters' discount and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of $1.63 per share, without giving effect to the potential exercise of the warrants offered hereby.

In addition, as of November 17, 2016, we had a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximately 450,170 shares of our common stock at a current weighted average exercise price of approximately $5.09; and

- options to purchase approximately 299,752 shares of our common stock at a current weighted average exercise price of approximately $18.20.

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

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

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

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

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

Our common stock has from time to time been "thinly-traded," meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or

more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share

price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

If the price of our common stock falls, it may be deemed to be a "penny stock," which may make it more difficult for investors to sell their shares due to suitability requirements.

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

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

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

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

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

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

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

On November 18, 2013, we entered into a purchase agreement (the "2013 Purchase Agreement") with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $10.6 million of our common stock, of which approximately $8.2 million worth of our common stock remains issuable as of the date of this prospectus. Concurrently with the execution of the 2013 Purchase Agreement, we issued 9,766 shares of our common stock to Lincoln Park as a partial fee for its commitment to purchase shares of our common stock under the 2013 Purchase

Agreement and 28,572 shares of common stock for an aggregate price of $600,000. From November 18, 2013 through the date of this prospectus, we sold 105,000 additional shares to Lincoln Park and issued 2,210 additional shares to Lincoln Park as additional commitment shares under the 2013 Purchase Agreement and received proceeds of $1,809,652. The shares that may be sold pursuant to the 2013 Purchase Agreement in the future may be sold by us to Lincoln Park at our discretion from time to time over the remaining term of approximately one week from the date of this prospectus, provided the registration statement registering the resale of shares sold to Lincoln Park under the 2013 Purchase

Agreement remains effective. The purchase price for the shares that we may sell to Lincoln Park under the 2013 Purchase Agreement will fluctuate based on the price of our common stock. We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of the 2013 Purchase Agreement, we would be unable to sell shares to Lincoln Park if and when the closing sale price of our common stock is below $10.00 per share, subject to adjustment as set forth in the 2013 Purchase Agreement.

On March 22, 2016, we entered into an additional purchase agreement (the "2016 Purchase Agreement") with 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 $10.3 million worth of our common stock remains issuable as of the date of this prospectus. 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 the date of this prospectus, we sold 260,000 shares to Lincoln Park and issued 7,135 additional shares to Lincoln Park as additional commitment shares under the 2016 Purchase Agreement and received proceeds of $1,712,320. 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 28 months from the date of this prospectus, 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 2013 Purchase Agreement or 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 2013 Purchase Agreement or 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 2013 Purchase Agreement or 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 the Registration Rights Agreement with Hy Biopharma, pursuant to which we have filed a registration statement with the SEC.

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

We may ultimately issue all, some or none of the additional shares of our common stock that may be issued pursuant to the purchase agreement. We are required to register any shares issued pursuant to the purchase agreement

for resale under the Securities Act. After any such shares are registered, the holders will be able to sell all, some or none of those shares. Therefore, issuances by us under the purchase agreement could result in substantial dilution to the interests of other holders of our common stock. Additionally, the issuance of a substantial number of shares of our common stock pursuant to the purchase agreement, or the anticipation of such issuances, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Our management will have broad discretion over the use of the net proceeds from this offering and we may use the net proceeds in ways with which you disagree or which do not produce beneficial results.

We currently intend to use the net proceeds from this offering to fund our research and development activities and for working capital and general corporate purposes (see "Use of Proceeds"). We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us or our stockholders. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, and results of operation.

Randall J. Kirk and Paolo Cavazza, together with their affiliates, will collectively beneficially own approximately 17% of our outstanding common stock after this offering and will continue to have substantial control over the company.

Upon completion of this offering, assuming 1,910,829 shares of common stock are sold in this offering, Randall J. Kirk and Paolo Cavazza, together with their affiliates, will beneficially own, in the aggregate, approximately 17% of our outstanding common stock. As a result, these stockholders, acting together, would have the ability to strongly influence the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control.

Risks Related to Our Reverse Stock Split

On October 7, 2016, we effected a one-for-ten reverse stock split of our outstanding common stock. However, the reverse stock split may not increase our stock price sufficiently and we may not be able to list our common stock and warrants on NASDAQ, in which case this offering may not be completed.

We expect that the reverse stock split of our outstanding common stock will increase the market price of our common stock sufficiently so that we will be able to meet the minimum listing requirements of NASDAQ. However, the effect of a reverse stock split upon the market price of our common stock cannot be predicted with certainty, and the results of reverse stock splits by companies in similar circumstances have been varied. It is possible that the market price of our common stock following the reverse stock split will not increase sufficiently for us to be in compliance with the minimum bid price requirement, or if it does, that such price will be sustained. If we are unable meet the minimum listing requirements, we will be unable to list our shares and warrants on NASDAQ, in which case this offering may not be completed.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock, we cannot assure you that we will be able to continue to comply with the minimum listing requirements of NASDAQ.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock to be in compliance with the minimum listing requirements of NASDAQ, there can be no assurance that the market price of

our common stock following the reverse stock split will remain at the level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the reverse stock split, the percentage decline may be greater than would occur in the absence of the reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and adversely affect our ability to meet or maintain NASDAQ's minimum listing requirements. In addition to specific listing and maintenance standards, NASDAQ has broad discretionary authority over the initial and continued listing of securities, which it could exercise with respect to the listing of our common stock.

Even if the reverse stock split increases the market price of our common stock, there can be no assurance that we will be able to comply with other continued listing standards of NASDAQ.

Even if the market price of our common stock increases sufficiently so that we comply with the minimum initial listing requirements, we cannot assure you that we will be able to comply with the other standards that we are required to meet in order to maintain a listing of our common stock on NASDAQ. Our failure to meet these requirements may result in our common stock being delisted from NASDAQ, irrespective of our compliance with the minimum bid price requirement.

The reverse stock split may decrease the liquidity of the shares of our common stock.

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split. In addition, the reverse stock split may increase the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following the reverse stock split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA AND MARKET INFORMATION

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

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

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

- the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our proposed products, including: (i) the timing, status and results of our or our commercial partners’ filings with the 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;

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

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

Industry Data and Market Information

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

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

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USE OF PROCEEDS

We estimate that our net proceeds from the sale of the common stock and warrants offered pursuant to this prospectus will be approximately $5.2 million, or approximately $6.1 million if the underwriters exercise in full their option to purchase additional shares of common stock and additional warrants, assuming a public offering price of $3.14 per share of common stock, which is based on the closing price of our common stock on November 17, 2016, and an assumed public offering price of $0.01 per warrant, and after deducting the underwriting discount and the estimated offering expenses that are payable by us.

We currently intend to use the net proceeds from this offering to fund our pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL and our pivotal Phase 2b/3 protocol of SGX942 for the treatment of oral mucositis in head and neck cancer patients, as well as for general working capital purposes. We have not yet determined the amount of the net proceeds to be used specifically for any purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from this offering. Pending any use as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

DIVIDEND POLICY

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

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

Our common stock is quoted on the OTCQB under the symbol "SNGX." The following table sets forth, 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. Prior to this offering, there was no trading market for the warrants.

	Price Range	
Period	High	Low
Year Ended December 31, 2014:		
First Quarter	$ 25.00	$ 17.50
Second Quarter	$ 22.90	$ 16.50
Third Quarter	$ 22.50	$ 16.70
Fourth Quarter	$ 20.90	$ 9.10
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 Ending December 31, 2016:		
First Quarter	$ 12.50	$ 6.20
Second Quarter	$ 9.00	$ 6.10
Third Quarter	$ 8.50	$ 5.60
Fourth Quarter (through November 17, 2016)	$ 8.10	$ 2.95

On November 17, 2016, the last reported price of our common stock quoted on the OTCQB was $3.14 per share. The OTCQB prices set forth above represent inter-dealer quotations, without adjustment for retail mark-up, mark-down or commission, and may not represent the prices of actual transactions. An application has been made to list the common stock and warrants on NASDAQ under the symbols "SNGX" and "SNGXW," respectively.

Transfer Agent

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

Holders of Common Stock

As of November 17, 2016, there were 346 holders of record of our common stock. As of such date, 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. A maximum of 300,000 shares of our common stock are available for issuance under the 2015 Equity Incentive Plan. The following table provides information, as of December 31, 2015 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.

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Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders(1)	276,861	$ 21.30	252,300
Equity compensation plans not approved by security holders	—	—	—
Total	276,861	$ 21.30	252,300

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

DILUTION

If you invest in our securities in this offering, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock in this offering and our pro forma as adjusted net tangible book value per share immediately after this offering. Net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the number of outstanding shares of our common stock.

Our pro forma net tangible book value as of September 30, 2016 was $3,426,242 or $0.90 per share of common stock, based upon 3,800,032 shares outstanding, after giving effect to (i) issuances of 44,283 shares of common stock for which we received $73,210 from October 1, 2016 through and immediately prior to the date of this prospectus and (ii) the remeasurement of the $1,324,909 warrant liability as of the date of the amendment to the terms of the warrants issued in the 2013 public offering, which resulted in an approximate $430,000 decrease in the carrying value of the warrant liability, which was recognized in the statement of operations on the date of the modification, and the reclassification of the warrant liability to equity. Assuming that our common stock in this offering is sold to the underwriters at a price of $3.14 per share, based on the closing price on November 17, 2016, the number of outstanding shares of our common stock, and without counting shares issuable upon the conversion or exercise of any notes, warrants or options, would increase by 1,910,829 shares (rounded to the nearest whole share), for a total of 5,710,861 shares of our common stock outstanding. After giving effect to the sale of the shares of common stock and warrants in this offering at the assumed public offering price of $3.14 per share (based upon the closing price on November 17, 2016) and $0.01 per warrant, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at September 30, 2016 would have been $8,644,573, or $1.51 per share. This represents an immediate increase in pro forma net tangible book value of approximately $0.61 per share to our existing stockholders, and an immediate dilution of $1.63 per share to investors purchasing shares and warrants in this offering. The following table illustrates the per share dilution:

Assumed public offering price per share of common stock together with a warrant (based upon the closing price on November 17, 2016)		$ 3.14
Pro forma net tangible book value per share as of September 30, 2016	$ 0.90	
Increase in pro forma net tangible book value per share after this offering	$ 0.61	
Pro forma as adjusted net tangible book value per share after this offering		$ 1.51
Dilution in pro forma net tangible book value per share to new investors		$ 1.63

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to $1.58 per share, representing an immediate increase to existing stockholders of $0.68 per share and an immediate dilution of $1.56 per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, new investors will experience further dilution.

A $1.00 increase (decrease) in the assumed public offering price of $3.14 per share, with the $0.01 price per warrant remaining the same, would increase (decrease) the pro forma as adjusted net tangible book value per share by $0.31, assuming the number of shares and warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Each 20% increase of the assumed number of shares of common stock and warrants offered by us, as set forth on the cover page of this prospectus, would increase (a) our pro forma as adjusted net tangible book value by approximately $1.1 million, (b) our pro forma as adjusted net tangible book value per share after this offering by $0.09 per share and (c) the dilution per share to new investors in this offering by $0.09, assuming a public offering price of $3.14 per share and $0.01 per warrant remain the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each 20% decrease of the assumed number of shares of common stock and warrants offered by us, as set forth on the cover page of this prospectus, would decrease (a) our pro forma as adjusted net tangible book value by approximately $1.1 million, (b) our pro forma as adjusted net tangible book value per share after this offering by $0.10 per share and (c) the dilution per share to new investors in this offering by $0.10, assuming a public offering price of $3.14 per share and $0.01 per warrant remain the same, and

after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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CAPITALIZATION

The following table sets forth our capitalization, as of September 30, 2016:

- on an actual basis, adjusted to reflect the reverse stock split of one-for-ten effective October 7, 2016;

- on a pro forma basis to give effect to the issuance of 44,283 shares of common stock for which we received $73,210 from October 1, 2016 through and immediately prior to the date of this prospectus; and

- on a pro forma as adjusted basis to give effect to (i) the issuance of common stock from October 1, 2016 through and immediately prior to the date of this prospectus, (ii) the remeasurement of the $1,324,909 warrant liability as of the date of the amendment to the terms of the warrants issued in the 2013 public offering, which resulted in an approximate $430,000 decrease in the carrying value of the warrant liability, which was recognized in the statement of operations on the date of the modification, and the reclassification of the warrant liability to equity and (iii) the sale of the securities in this offering at the assumed public offering price of $3.14 per share (the closing price of the common stock on November 17, 2016) and $0.01 per warrant, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

Investors should consider this table in conjunction with our financial statements and the notes to those financial statements included elsewhere in this prospectus.

	As of September 30, 2016		
	Actual	Pro Forma	Pro Forma As Adjusted[(1)]
Shareholders' equity:			
Preferred stock, 350,000 shares authorized; none issued or outstanding	—		
Common stock, $.001 par value; 10,000,000 shares authorized; issued and outstanding at September 30, 2016, 3,754,224 shares actual, 3,800,032 pro forma and 5,710,861 pro forma, as adjusted	**$ 3,755**	**$ 3,800**	**$ 5,711**
Additional paid-in capital	**151,959,679**	**152,032,844**	**158,142,121**
Accumulated deficit	**(149,793,003)**	**(149,793,003)**	**(149,360,954)**
Total shareholders' equity	**$ 2,170,431**	**$ 2,243,641**	**$ 8,786,878**
Total capitalization	**$ 2,170,431**	**$ 2,243,641**	**$ 8,786,878**

(1) A $1.00 increase or decrease in the assumed public offering price of $3.14 per share, with the $0.01 price per warrant remaining the same, would increase or decrease each of additional paid-in capital, total stockholders' deficiency and total capitalization on a pro forma as adjusted basis by approximately $1.8 million, assuming the number of shares and warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each 20% increase (decrease) in the assumed number of shares of common stock and warrants offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of additional paid-in capital, total stockholders' deficiency and total capitalization by approximately $1.1 million, assuming a public offering price of $3.14 per share and $0.01 per warrant remain the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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 light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We plan to use the funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grant from NIAID to advance the development of OrbeShield® for the treatment of GI ARS.

An outline for 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 to collect the long-term follow-up safety data from the SGX942 Phase 2 proof-of-concept study for the treatment of oral mucositis in head and neck cancer patients and publish the findings from this study;

- Obtain agreement from the United States Food and Drug Administration (the "FDA") on a pivotal Phase 2b/3 protocol 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;

- 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 under the BARDA contract and with NIAID 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.

Critical Accounting Policies

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

Intangible Assets

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

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

Fair Value of Financial Instruments

FASB ASC 820 — *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us on December 31, 2015 and on September 30, 2016. Accordingly, the estimates presented in the 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, notes payable and accrued compensation approximate their fair value based on the short-term maturity of these instruments. We recognize all derivative financial instruments as assets or liabilities in the financial statements and measure them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with our June 2013 registered public offering were accounted for as derivatives.

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 are recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. All other warrants issued were indexed to our own stock and therefore are accounted for as equity instruments for 2016, 2015 and 2014.

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 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.

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 2016, 2015 and 2014 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 bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including our current and past performance, the market environment in which we operate, 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, 2016 due to the net operating losses incurred by us since its inception. We recognize 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, 2015 and 2014. Additionally, we have not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at September 30, 2016 and December 31, 2015 and 2014.

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, 2016 Compared to September 30, 2015

For the three months ended September 30, 2016, we had a net loss of $1,673,217 as compared to net income of $2,774,348 for the same period in the prior year, representing an increase in the net loss of $4,447,565 or 160%. For the nine months ended September 30, 2016, we had a net loss of $2,915,424 as compared to a net loss of $5,772,668 for the same period in the prior year, representing a decrease of $2,857,244 or 49%. Included in the net loss for the three months and nine months ended September 30, 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. The change in the fair

value of the warrant liability for the three months ended September 30, 2016 and 2015 resulted in an expense of ($176,293) and income of $4,047,742, respectively. For the nine months ended September 30, 2016 and 2015, the change in fair value resulted in $1,109,192 of income and ($907,368) of expense, respectively.

For the three and nine months ended September 30, 2016, revenues 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 three months ended September 30, 2016, we had revenues of $2,959,254 as compared to $3,879,675

for the same period in the prior year, representing a decrease of $920,421 or 24%. The decrease in revenues is a result of certain contracted fixed and management fees being recognized from the achievement of development milestones. For the nine months ended September 30, 2016, we had revenues of $8,750,291 as compared to $5,795,788 for the same period in the prior year, representing an increase of $2,954,503 or 51%. The increase in revenues during the nine month period was a result of increased activities performed under our government contracts associated with OrbeShield® and RiVax™.

We incurred costs related to those revenues for the three months ended September 30, 2016 and 2015 of $2,630,046 and $3,050,814, respectively, representing a decrease of $420,768, or 14%. For the nine months ended September 30, 2016, costs related to revenues were $7,204,920 as compared to $4,394,915 for the same period in the prior year, representing an increase of $2,810,005 or 64%. These costs relate to allocated employee costs and payments due to subcontractors in connection with research performed pursuant to the contracts and grants.

Our gross profit for the three months ended September 30, 2016 was $329,208 or 11%, as compared to $828,861 or 21%, for the same period in 2015, representing a decrease of $499,653 or 60%. For the nine months ended September 30, 2016, gross profit was $1,545,371 or 18%, as compared to $1,400,873 or 25%, for the same period in the prior year, representing an increase of $144,498 or 10%. The decrease in gross profit percentage is attributable to a larger percentage of reimbursable costs not available for contracted fixed management fee reimbursement. The management fee associated with certain contracts are payable upon the achievement of development milestones.

Research and development expenses decreased by $81,752 or 6%, to $1,177,263 for the three months ended September 30, 2016 as compared to $1,259,015 for the same period in 2015. For the nine months ended September 30, 2016, research and development expenses were $3,433,595 compared to $3,731,813 for the same period in 2015, reflecting a decrease of $298,218 or 8%. The decrease is primarily due to a decrease in manufacturing for Pediatric Crohn's, 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 $188,750 or 22%, to $650,762 for the three months ended September 30, 2016 as compared to $839,512 for the same period in 2015. For the nine months ended September 30, 2016, general and administrative expenses were $2,526,255 compared to $2,531,744 for the same period in 2015, reflecting a nominal decrease. The decrease for the three months ended September 30, 2016 is primarily related to outside professional fees.

Total other income (expense) for the three months ended September 30, 2016 was ($174,400) as compared to $4,044,014 for the same period in 2015, reflecting a change of $4,218,414. For the nine months ended September 30, 2016 and 2015, total other income (expense) was $1,499,055 and ($909,984), respectively, reflecting a change of $2,409,039. The change in both the three and nine months ended September 30, 2016 is primarily due to the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering. In addition, $390,599 is 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 second quarter of 2016 that the amount was no longer considered outstanding by the counterparty and therefore reversed the amount accrued, resulting in other income.

Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

For the year ended December 31, 2015, we had a net loss of $7,831,230 as compared to a net loss of $6,706,972 for the prior year, representing an increased loss of $1,124,258 or 17%. Included in the net loss for December 31, 2015 is a non-cash expense of $1,201,870 versus a non-cash gain of $3,436,195 for December 31, 2014 which represents the change in the fair value of the warrant liability related to warrants issued in connection with our registered public offering in June 2013.

For the year ended December 31, 2015 and 2014, revenues and associated costs relate to government contracts and grants awarded in support of the development of ThermoVax®, RiVax™ GI-ARS and OrbeShield® in GI ARS. For the year ended December 31, 2015, we had revenues of $8,768,390 as compared to $7,043,016 for the prior year, representing an increase of $1,725,374 or 24%. The increase in revenues was a result of research and development activities performed under our government contracts associated with OrbeShield® and RiVax™.

We incurred costs related to contract and grant revenues in the year ended December 31, 2015 and 2014 of $6,882,204 and $5,313,855, respectively, representing an increase of $1,568,349 or 30%. These costs primarily relate to payments made to subcontractors and allocated employee costs in connection with research performed pursuant to contracts and grants. The fluctuations are due to the development activity performed on the contracts and grants discussed above.

Our gross profit for the year ended December 31, 2015 was $1,886,186 as compared to $1,729,161 for the prior year, representing an increase of $157,025 or 9%. This increase is due primarily to the increased activity in our OrbeShield® and RiVax™ contracts.

Research and development, including acquired in-process research and development costs, decreased by $3,686,696 or 41%, to $5,399,839 for the year ended December 31, 2015 as compared to $9,086,535 for the prior year. This decrease is primarily related to the 2014 acquisition of Hypericin, SGX301, for which we issued common stock with a value of $3,750,000 and paid cash of $275,000 which was recognized as acquired in-process research and development expense. During 2015, we also completed the Phase 2 clinical trial with SGX942 for patients suffering from oral mucositis associated with their chemoradiation therapy (“CRT”) for head and neck cancer and in December 2015, initiated the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL.

General and administrative expenses increased by $192,648 or 6%, to $3,596,623 for the year ended December 31, 2015, as compared to $3,403,975 for the prior year. This increase is primarily related to an increase in outside professional services.

Other income (expense) for the year ended December 31, 2015 was $(1,209,887) as compared to $3,437,505 for the prior year. The change is primarily related to non-cash expense of $(1,201,870) which represents the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering for the year ended December 31, 2015 as compared to non-cash income of $3,436,195 from the change for the year ended December 31, 2014.

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, 2015, we sold New Jersey NOL carryforwards, resulting in the recognition of $488,933 of income tax benefit, net of transaction costs as compared to $616,872 for the year ended December 31, 2014. There can be no assurance as to the continuation or magnitude of this program in future years.

Business Segments

We maintain two active business segments for the year ended December 31, 2015 and December 31, 2014: Vaccines/BioDefense and BioTherapeutics.

Revenues for the Vaccines/BioDefense business segment for the year ended December 31, 2015 were $8,754,418 as compared to $6,756,388 for the year ended December 31, 2014, representing an increase of $1,998,030 or 30%. This increase in revenues was a result of our OrbeShield® and RiVax™ contracts. Revenues for the BioTherapeutics business segment for the year ended December 31, 2015 were $13,972 as compared to $286,628 for the year ended December 31, 2014, representing a decrease of $272,656 or 95%. This decrease is primarily 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, 2015 was $1,263,709 as compared to $807,164 for the year ended December 31, 2014. 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, 2015 was $4,487,988 as compared to $7,674,381 for the year ended December 31, 2014, representing a decrease of $3,186,393. This decreased loss is due primarily to the 2014

acquisition of Hypericin, SGX 301, for which we issued common stock with a value of $3,750,000 and paid cash of $275,000 which was recognized as acquired in-process research and development expense, offset by expenses in 2015 related to the Phase 2 clinical trial with SGX942 for patients suffering from oral mucositis associated with their CRT for head and neck cancer and 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, 2015 was $39,925 as compared to $39,625 for the year ended December 31, 2014. Amortization and

depreciation expense for the BioTherapeutics business segment for the year ended December 31, 2015 was $199,661 as compared to $199,196 for the year ended December 31, 2014.

Financial Condition and Liquidity

Cash and Working Capital

As of September 30, 2016, we had cash and cash equivalents of $5,655,200 as compared to $4,921,545 as of December 31, 2015, representing an increase of $733,655 or 15%. As of September 30, 2016, we had working capital of $3,319,982 which excludes a non-cash warrant liability of $1,324,909, 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 $1,140,288 or 52%. The increase is primarily related to the increase in cash as a result of the proceeds received from our stock purchase agreement with SciClone.

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 Capital Fund, LLC 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 approximately $35.1 million in active contract and grant funding still available to support our associated research programs in 2016 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 these programs with various funding agencies;

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

- We will pursue NOL sales in the State of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $488,933 in proceeds from the sale of NJ NOL in 2015, we expect to receive $530,143 in net proceeds in 2016. We expect to participate in the program during 2017 and beyond as the program is available;

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

- We have $8.2 million available from equity facilities expiring in November 2016 and $10.4 million from equity facilities expiring in March 2019; and

- We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities 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.

Reverse Stock Split

On October 7, 2016, we completed a reverse stock split of our issued and outstanding shares of common stock at a ratio of one-for-ten, whereby, every ten shares of our common stock were exchanged for one share of our common

stock. Our common stock began trading on the OTCQB on a reverse split basis on October 7, 2016. All share and per share data have been restated to reflect this reverse stock split.

Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately $12.0 million before any contract or grant reimbursements, of which $5.8 million

relates to the BioTherapeutics business and $6.2 million relates to the Vaccines/BioDefense business. We anticipate contract and grant revenues in the next 12 months of approximately $6.2 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:

	2016		**2015**	
Research & Development Expenses				
Oral BDP	**$**	**210,038**	$	548,061
RiVax™ and ThermoVax® Vaccines		**228,274**		381,172
Dusquetide (SGX942)		**1,030,740**		1,179,335
SGX943		**1,628**		10,671
SGX301		**1,559,480**		1,310,279
Other		**403,435**		302,295
Total	**$**	**3,433,595**	$	3,731,813
Reimbursed under Government Contracts and Grants				
OrbeShield®	**$**	**3,254,204**	$	3,748,875
RiVax™ and ThermoVax® Vaccines		**3,950,365**		561,297
Other		**351**		84,743
Total		**7,204,920**		4,394,915
Grand Total	**$**	**10,638,515**	$	8,126,728

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

	2015		2014	
Research & Development Expenses				
Oral BDP	$	74,543	$	561,655
RiVax™ & ThermoVax® Vaccines		622,908		846,870
Dusquetide (SGX94)		2,216,632		2,820,807
SGX943		10,671		19,378
SGX301		2,141,175		4,369,585
Other		333,910		468,240
Total	$	5,399,839	$	9,086,535
Reimbursed under Government Contracts and Grants				
OrbeShield®	$	5,240,377	$	4,100,663
RiVax™ & ThermoVax® Vaccines		1,557,082		930,573
Other		84,745		282,619
Total	$	6,882,204	$	5,313,855
Grand Total	$	12,282,043	$	14,400,390

Contractual Obligations

We have commitments of approximately $416,667 as of September 30, 2016 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, 2016, 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.

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, 2016, no milestone payments have been made or accrued.

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

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

Year	Research and Development	Property and Other Leases	Total
October 1 through December 31, 2016	$ 16,667	$ 39,333	$ 56,000
2017	100,000	151,000	251,000
2018	100,000	52,000	152,000
2019	100,000	—	100,000
2020	100,000	—	100,000
Total	$ 416,667	$ 242,333	$ 659,000

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 light for the treatment of cutaneous T-cell lymphoma ("CTCL"), our first-in-class innate defense regulator technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201).

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs currently is supported by our heat stabilization technology, known as ThermoVax®, under existing and on-going government contract funding. With the government contract from the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of RiVax™ to protect against exposure to ricin toxin. We plan to use the funds received under our awarded government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and grants from NIAID to advance the development of OrbeShield® for the treatment of GI ARS.

An outline for 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 to collect the long-term follow-up safety data from the SGX942 Phase 2 proof-of-concept study for the treatment of oral mucositis in head and neck cancer patients and publish the findings from this study;

- Obtain agreement from the United States Food and Drug Administration (the "FDA") on a pivotal Phase 2b/3 protocol 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;

- 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 under the BARDA contract and with NIAID 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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Our Product Candidates in Development

The following tables summarize our product candidates under development:

BioTherapeutic Product Candidates

Soligenix Product Candidate	Therapeutic Indication	Stage of Development
SGX301	Cutaneous T-Cell Lymphoma	Phase 2 trial completed; demonstrated significantly higher response rate compared to placebo; Phase 3 clinical trial initiated in the second half of 2015, with data expected in the second half of 2017
SGX942	Oral Mucositis in Head and Neck Cancer	Phase 2 trial initiated in the second half of 2013, with positive preliminary results reported in the second half of 2015 and long-term data expected in the second half of 2016; seek to obtain FDA agreement on the Phase 2b/3 protocol in the first half of 2017
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed in June 2013, efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety profile demonstrated; Phase 3 clinical trial planned for the first half of 2017, with data expected in the second half of 2018