

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

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

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SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

Soligenix, Inc.

29 Emmons Drive, Suite C-10

Princeton, New Jersey 08540

(609) 538-8200

2834

(Primary Standard Industrial  
Classification Code Number)

41-1505029

(I.R.S. Employer  
Identification No.)

(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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Leslie J. Croland, Esq.  
Driscoll R. Ugarte, Esq.  
Duane Morris LLP  
200 South Biscayne Boulevard  
Suite 3400  
Miami, Florida 33131-2318  
(305) 960-2200

Leslie Marlow, Esq.  
Hank Gracin, Esq.  
Patrick J. Egan, Esq.  
Gracin & Marlow, LLP  
The Chrysler Building  
405 Lexington Avenue, 26<sup>th</sup> Floor  
New York, NY 10174  
(212) 907-6457

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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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

	Proposed maximum aggregate offering price <sup>(1)</sup>	Amount of registration fee <sup>(1)(3)</sup>	
Title of each class of securities to be registered			
Common Stock, \$0.001 par value <sup>(2)(3)</sup>			
Common Stock Purchase Warrants			
Shares of Common Stock, \$0.001 par value per share, underlying Common Stock Purchase Warrants <sup>(2)(3)</sup>			
Representative's Warrant <sup>(5)</sup>			
Shares of Common Stock underlying Representative's Warrant <sup>(2)(3)(6)</sup>			
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	\$	\$	\$

(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.

**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

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\*\* 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 <sup>(1)</sup>	\$ (0.90 )	\$ (2.26 )	\$ (3.00 )	\$ (3.25 )
Diluted net loss per share <sup>(1)</sup>	\$ (1.20 )	\$ (2.26 )	\$ (3.00 )	\$ (4.30 )
Basic weighted average common shares outstanding <sup>(1)</sup>	3,245,653	2,553,930	2,606,577	2,063,842
Diluted weighted average common shares outstanding <sup>(1)</sup>	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 <sup>(1)</sup>
<b>Balance Sheet Data:</b>		
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;

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- 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

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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

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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

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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 15c-1 through 15c-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 to 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.



- 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.”



## 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.

Period	Price Range	
	High	Low
<b><i>Year Ended December 31, 2014:</i></b>		
First Quarter	\$ 25.00	\$ 17.50
Second Quarter	\$ 22.90	\$ 16.50
Third Quarter	\$ 22.50	\$ 16.70
Fourth Quarter	\$ 20.90	\$ 9.10
<b><i>Year Ended December 31, 2015:</i></b>		
First Quarter	\$ 23.00	\$ 9.80
Second Quarter	\$ 29.50	\$ 13.60
Third Quarter	\$ 24.80	\$ 9.10
Fourth Quarter	\$ 14.40	\$ 4.40
<b><i>Year Ending December 31, 2016:</i></b>		
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 <sup>(1)</sup>
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:

	<b>2016</b>	<b>2015</b>
<b><i>Research &amp; Development Expenses</i></b>		
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
<b><i>Reimbursed under Government Contracts and Grants</i></b>		
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
<b>Research &amp; Development Expenses</b>		
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
<b>Reimbursed under Government Contracts and Grants</b>		
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
<b>Contractual Obligations</b>		

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

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## BUSINESS

### Our Business Overview

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

Our BioTherapeutics business segment is developing a novel photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible 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.





**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

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\*\* 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.

#### BioTherapeutics Overview

SGX301 — for Treating Cutaneous T-Cell Lymphoma

SGX301 is a novel, photodynamic therapy that utilizes safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated

by fluorescent light 16 to 24 hours later. Hypericin is also found in several species of Hypericum plants, although the drug used in SGX301 is chemically synthesized by a proprietary manufacturing process and not extracted from plants. Importantly, hypericin is optimally activated with visible light thereby avoiding the negative consequences of ultraviolet light. Other light therapies using UVA light result in serious adverse effects including secondary skin cancers.

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

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

SGX301 has received orphan drug designation as well as Fast Track designation from the FDA. The Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. In addition to providing a seven-year term of market exclusivity for SGX301 upon final FDA approval, orphan drug designation also positions us to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of FDA user fees for the potential submission of a New Drug Application (“NDA”) for SGX301, and certain tax credits. In addition, Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast Track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit a NDA for SGX301 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review. SGX301 also was granted orphan drug designation from the European Medicines Agency Committee for Orphan Medical Products.

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

We estimate the potential worldwide market for SGX301 is in excess of \$250 million for all applications, including the treatment of CTCL. This potential market information is a forward-looking statement, and investors are urged not to place undue reliance on this statement. While we have determined this potential market size based on assumptions

that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. See “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements — Industry Data and Market Information.”

## Cutaneous T-Cell Lymphoma

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

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

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

## Dusquetide

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

Dusquetide is based on a new class of short, synthetic peptides known as IDRs that have a novel mechanism of action in that it is simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. IDRs represent a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, sequestosome-1, also known as p62, which has a pivotal function in signal transduction during activation and control of the innate defense system. Preclinical data indicate that IDRs may be active in models of a wide range of therapeutic indications including life-threatening bacterial infections as well as the severe side-effects of chemo- and radiation-therapy.

Dusquetide has demonstrated efficacy in numerous animal disease models including mucositis, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. Dusquetide was shown to have a good safety profile and well-tolerated in all dose groups when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. Dusquetide is the subject of an open Investigational New

Drug (“IND”) application which has been cleared by the FDA. We believe that market opportunities for dusquetide include mucositis, acute methicillin resistant *Staphylococcus aureus* (MRSA) bacterial infections, acinetobacter, melioidosis and acute radiation syndrome.

SGX942 — for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is our product candidate containing our IDR technology, dusquetide, targeting the treatment of oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical

need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA.

We initiated a Phase 2 clinical study of SGX942 for the treatment of oral mucositis in head and neck cancer patients in the second half of 2013. We completed enrollment in this trial in the second half of 2015, and in December 2015 released positive preliminary results. In this Phase 2 proof-of-concept clinical study that enrolled 111 patients, SGX942, at a dose of 1.5 mg/kg, successfully reduced the median duration of severe oral mucositis by 50%, from 18 days to 9 days ( $p=0.099$ ) in all patients and by 67%, from 30 days to 10 days ( $p=0.040$ ) in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. The p-values met the prospectively defined statistical threshold of  $p<0.1$  in the study protocol. In addition to identifying the optimal dose of 1.5 mg/kg, this study achieved all objectives, including increased incidence of “complete response” of tumor at the one month follow-up visit (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and decreases in infection rate were also observed with SGX942 treatment, consistent with the preclinical results observed in animal models, and are being further evaluated. SGX942 was found to be generally safe and well tolerated, consistent with the safety profile observed in the prior Phase 1 study conducted in 84 healthy volunteers. Long-term follow-up evaluations are ongoing with final results expected in the fourth quarter of 2016. Data from this Phase 2 trial was published online in the Journal of Biotechnology. The publication also delineates the supportive nonclinical data in this indication, demonstrating consistency in the qualitative and quantitative biological response, including dose response, across the nonclinical and clinical data sets. The results are available at the following link:<http://authors.elsevier.com/sd/article/S01681656116315668>.

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

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

### Oral Mucositis

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

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

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



## Oral BDP

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

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

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

### SGX203 — for Treating Pediatric Crohn's Disease

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

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

### Pediatric Crohn's Disease

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

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

Crohn's disease presents special challenges for children and teens. In addition to bothersome and often painful symptoms, the disease can stunt growth, delay puberty, and weaken bones. Crohn's disease symptoms may sometimes

prevent a child from participating in enjoyable activities. The emotional and psychological issues of living with a chronic disease can be especially difficult for young people.

SGX201 — for Preventing Acute Radiation Enteritis

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. In 2012, we completed a Phase 1/2 clinical trial testing SGX201 in prevention of acute radiation enteritis. Patients with rectal cancer scheduled

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

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

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

#### Acute Radiation Enteritis

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

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

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

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

#### Vaccines/BioDefense Overview

ThermoVax® — Thermostability Technology

Our thermostability technology, ThermoVax®, is a novel method of rendering aluminum salt, (known colloquially as Alum), adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax® lies in its potential ability to eliminate the need for cold-chain production, transportation, and storage for Alum adjuvanted vaccines. This would relieve companies of the high costs of producing and maintaining vaccines under refrigerated conditions. Based on historical reports from the World Health Organization and other scientific reports, we believe that a meaningful proportion of vaccine doses globally are wasted due to excursions from required cold chain temperature ranges. This is due to the fact that most Alum adjuvanted vaccines need to be maintained at between 2 and 8 degrees Celsius (“C”) and even brief excursions from

this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. We believe that the savings realized from the elimination of cold chain costs and related product losses would significantly increase the profitability of vaccine products. We believe that elimination of the cold chain could further facilitate the use of these vaccines in the lesser developed parts of the world. ThermoVax® has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

ThermoVax® development was supported pursuant to our \$9.4 million NIAID grant enabling development of thermo-stable ricin (RiVax™) and anthrax (VeloThrax®) vaccines. Proof-of-concept preclinical studies with ThermoVax® indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with our aluminum-adjuvanted ricin toxin vaccine, RiVax™ and our aluminum-adjuvanted anthrax vaccine, VeloThrax®. Each vaccine was manufactured under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the key antigen. When RiVax™ was kept at 40 degrees C (104 degrees Fahrenheit) for up to one year, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. In contrast, animals that were vaccinated with the liquid RiVax™ vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C. When VeloThrax® was kept for up to 16 weeks at 70 degrees C, it was able to develop a potent antibody response, unlike the liquid formulation kept at the same temperature. Moreover, we have also demonstrated the compatibility of our thermostabilization technology with other secondary adjuvants such as TLR-4 agonists. Additionally, the University of Colorado conducted a study that demonstrated a heat stable vaccine formulation of a human papillomavirus (“HPV”) vaccine. The work was conducted by Drs. Randolph and Garcea and demonstrated the successful conversion of a commercial virus-like particle-based vaccine requiring cold chain storage to a subunit, alum-adjuvanted, vaccine which is stable at ambient temperatures. This work, funded by a University of Colorado seed grant and the Specialized Program of Research Excellence in cervical cancer, is the first demonstration of the utility of ThermoVax® technology for the development of a subunit based commercial vaccine. The HPV vaccine formulation was found to be stable for at least 12 weeks at 50 degrees C. In the study, mice immunized with the ThermoVax®-stabilized HPV subunit vaccine were also found to achieve immune responses similar to the commercial HPV vaccine, Cervarix®, as measured by either total antibody levels or neutralizing antibody levels. Moreover, whereas the immune responses to Cervarix® were reduced after storage for 12 weeks at 50 degrees C, the ThermoVax® formulated vaccine retained its efficacy. The results were published online in the European Journal of Pharmaceutics and Biopharmaceutics. See <http://www.sciencedirect.com/science/article/pii/S0939641115002416>.

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

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

of multivalent vaccines (e.g., combination ricin-anthrax vaccine).

RiVax™ — Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin and, if approved, would be the first ricin vaccine. The immunogen in RiVax™ induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin.

RiVax™ has demonstrated statistically significant ( $p < 0.0001$ ) preclinical survival results in a lethal aerosol exposure non-human primate model (Roy et al, 2015, Thermostable ricin vaccine protects rhesus macaques against aerosolized ricin: Epitope-specific neutralizing antibodies correlate with protection, PNAS USA March 24, 2015), and has also been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies that we believe may protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial, which was completed in September 2012 and was sponsored by University of Texas Southwestern Medical Center (“UTSW”), evaluated a more potent formulation of RiVax™ that contained an aluminum adjuvant (Alum). The results of the Phase 1b study indicated that Alum adjuvanted RiVax™ was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax™. The outcomes of this second study were published in the Clinical and Vaccine Immunology (Vitetta et al., 2012, Recombinant Ricin Vaccine Phase 1b Clinical Trial, Clin. Vaccine Immunol. 10:1697-9). We have adapted the original manufacturing process for the immunogen contained in RiVax™ for thermostability and large scale manufacturing and are further establishing correlates of the human immune response in non-human primates. We have initiated a development agreement with Emergent BioSolutions, Inc. to implement a commercially viable, scalable production technology for the RiVax™ drug substance protein antigen.

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

RiVax™ has been granted orphan drug designation by the FDA for the prevention of ricin intoxication.

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

## Ricin Toxin

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

The Centers for Disease Control and Prevention has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein

synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. The recent ricin threat to government officials has heightened the awareness of this toxic threat. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.



## OrbeShield® — for Treating GI Acute Radiation Syndrome

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

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

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. We are seeking to treat the same type of toxicity in our acute radiation enteritis clinical program with SGX201. As a result, we believe that OrbeShield® has the potential to be a “dual use” compound, a desirable characteristic which is a specific priority of BARDA for ARS and other medical countermeasure indications. The FDA has cleared the IND application for OrbeShield® for the mitigation of morbidity and mortality associated with GI ARS.

In September 2013, we received two government contracts from BARDA and NIAID for the advanced preclinical and manufacturing development of OrbeShield® leading to FDA approval to treat GI ARS. The BARDA contract contains a two year base period with two contract options, exercisable by BARDA, for a total of five years and up to \$26.3 million. The NIAID contract consists of a one year base period and two contract options, exercisable by NIAID, for a total of three years and up to \$6.4 million. Previously, development of OrbeShield® had been largely supported by a \$1 million NIH grant to our academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, we received an SBIR grant from NIAID of approximately \$600,000 to support further preclinical development of OrbeShield® for the treatment of acute GI ARS. The FDA has given OrbeShield® orphan drug designation and Fast Track designation for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

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

## GI Acute Radiation Syndrome

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

believe there is an urgent medical need for specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

SGX943 — for Treating Melioidosis

SGX943 uses the same active ingredient, dusquetide, as contained in SGX942. SGX943 is being developed in preclinical studies as a potential treatment for melioidosis. Because SGX943 directly targets the innate immune system (and does not attempt to kill the bacteria directly), we believe it is particularly relevant for antibiotic-resistant bacteria.

The bacteria which causes melioidosis, *Burkholderia pseudomallei*, is known to be resistant to most antibiotics and to require prolonged treatment with the few antibiotics that do work. In February 2014, we were awarded a one-year NIAID SBIR award of approximately \$300,000 to further evaluate SGX943 as a potential treatment for melioidosis. Preclinical results to date have demonstrated that SGX943 treatment, in combination with standard of care antibiotics such as doxycycline, can statistically significantly enhance survival in a lethal murine pneumonic melioidosis model ( $p < 0.001$ ).

## Melioidosis

Melioidosis is a potentially fatal infection caused by the Gram-negative bacillus, *Burkholderia pseudomallei* (“Bp”). Highly resistant to many antibiotics, Bp can cause an acute disease characterized by a fulminant pneumonia and a chronic condition that can recrudescence. There is no preventive vaccine or effective immunotherapy for melioidosis. We believe that there is an unmet medical need for improved prevention and therapy.

Bp infection (melioidosis) is a major public health concern in the endemic regions of Southeast Asia and Northern Australia. In Northeast Thailand, which has the highest incidence of melioidosis, the mortality rate associated with Bp infection is over 40 percent, making it the third most common cause of death from infectious disease in that region after HIV/AIDS and tuberculosis. Bp activity is seen in Southeast Asia, South America, Africa, the Middle East, India, and Australia. The highest pockets of disease activity occur in Northern Australia and Northeast Thailand with increasing recognition of disease activity in coastal regions of India.

Beyond its public health significance, Bp and the closely-related *Burkholderia mallei* (“Bm”) are considered possible biological warfare agents by the DHHS because of the potential for widespread dissemination through aerosol. Bp like its relative Bm, the cause of Glanders, was studied by the U.S. as a potential biological warfare agent, but was never weaponized. It has been reported that the Soviet Union was also experimenting with Bp as a biological warfare agent. Both Bp and Bm have been designated high priority threats by the DHHS in its PHEMCE Strategy released in 2012 and are classified as Category B Priority Pathogens by NIAID.

## The Drug Approval Process

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

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

Clinical trials are normally done in three phases, although the phases may overlap. Phase 1 trials are smaller trials concerned primarily with metabolism and pharmacologic actions of the drug and with the safety of the product. Phase 2 trials are designed primarily to demonstrate effectiveness and safety in treating the disease or condition for which the product is indicated. These trials typically explore various doses and regimens. Phase 3 trials are expanded clinical

trials intended to gather additional information on safety and effectiveness needed to clarify the product's benefit-risk relationship and generate information for proper labeling of the drug, among other things. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension or termination of clinical trials if an unwarranted risk is presented to patients. When data is required from long-term use of a drug following its approval and initial marketing, the FDA can require Phase 4, or post-marketing, studies to be conducted.

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

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

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

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

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

## Orphan Drug Designation

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

## Fast Track Designation and Accelerated Approval

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

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

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

## Pediatric Information

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



### False Claims Laws

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

### Anti-Kickback Laws

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

### United States Healthcare Reform

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

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

### Third-Party Suppliers and Manufacturers

Drug substance and drug product manufacturing is outsourced to qualified suppliers. We do not have manufacturing capabilities/infrastructure and do not intend to develop the capacity to manufacture drug products substances. We have agreements with third-party manufacturers to supply bulk drug substances for our product candidates and with third parties to formulate, package and distribute our product candidates. Our employees include professionals with expertise in pharmaceutical manufacturing development, quality assurance and third party supplier management who oversee work conducted by third-party companies. We believe that we have on hand or can easily obtain sufficient amounts of product candidates to complete our currently contemplated clinical trials. All of the drug substances used in our product candidates currently are manufactured by single suppliers. While we have not experienced any supply

disruptions, the number of manufacturers of the drug substances is limited. In the event it is necessary or advisable to acquire supplies from alternative suppliers, assuming commercially reasonable terms could be reached, the challenge would be the efficient transfer of technology and know-how from current manufactures to the new supplier. Formulation and distribution of our finished product candidates also currently are conducted by single suppliers but we believe that alternative sources for these services are readily available on commercially reasonable terms, subject to the efficient transfer of technology and know-how from current suppliers to the new supplier.

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

#### Marketing and Collaboration

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

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

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

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

We also entered into a common stock purchase agreement with SciClone pursuant to which we sold 352,942 shares of our common stock to SciClone for approximately \$8.50 per share, for an aggregate price of \$3,000,000. As part of the

transaction, we granted SciClone certain demand registration rights, and SciClone agreed, subject to certain exceptions, not to pledge, sell or otherwise transfer or dispose of, or enter into any swap or other arrangement that transfers any of the economic consequences of ownership of, the shares purchased for at least one year from September 9, 2016.

## Competition

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

### SGX301 Competition

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

### SGX94/942 Competition

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

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

### Oral BDP Competition

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

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

### ThermoVax® Competition

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

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

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

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

#### Vaccines/BioDefense Competition

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

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

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

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

#### Patents and Other Proprietary Rights

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

technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

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

In 2014, we acquired a novel photodynamic therapy that utilizes safe visible light for activation, which we refer to as SGX301. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. As part of the acquisition, we acquired a license agreement relating to the use of photo-activated hypericin, composition of matter patent for SGX301 (U.S. patent 8,629,302) and additional issued and pending applications, both in the US and abroad. U.S. patent 8,629,302 is expected to expire in June 2032.

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

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

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

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

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

RiVax™ is the subject of three issued U.S. patent numbers 6,566,500, 6,960,652, and 7,829,668, all titled “Compositions and methods for modifying toxic effects of proteinaceous compounds.” This patent family includes composition of matter claims for the modified ricin toxin A chain which is the immunogen contained in RiVax™, and issued in 2003, 2005 and 2010 respectively. The initial filing date of these patents is March 2000 and they are expected to expire in March 2020. The issued patents contain claims that describe alteration of sequences within the ricin A

chain that affect vascular leak, one of the deadly toxicities caused by ricin toxin. Another U.S. patent number 7,175,848 titled “Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin,” was filed in October of 2000 and is expected to expire in October 2020.

#### SGX301 License Agreement

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

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

#### SGX94 License Agreements

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

#### Oral BDP License Agreement

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

equal to 3% of net sales of the covered products and (iv) pay Dr. McDonald \$400,000 in cash upon an approval of oral BDP by the European Medicines Agency.

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

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

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

#### ThermoVax® License Agreement

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

#### RiVax™ License Agreement

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

#### Research and Development Expenditure

We spent approximately \$3.4 million and \$3.7 million in the nine months ended September 30, 2016 and 2015, respectively, and \$5.4 million and \$9.1 million in the years ended December 31, 2015 and 2014, respectively, on research and development. The amounts we spent on research and development per product during the nine months ended September 30, 2016 and 2015 and the years ended December 31, 2015, and 2014 are set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus.

#### Employees

As of September 30, 2016, we had 19 full-time employees, 8 of whom are MDs/PhDs.



## Properties

We currently lease approximately 5,200 square feet of office space at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540. This office space currently serves as our corporate headquarters. In December 2014, we entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months 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 will increase to approximately \$12,460 per month, or approximately \$21.13 per square foot for the remainder of the lease. Our office space is sufficient to satisfy our current needs.

## Legal Proceedings

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

## MANAGEMENT

The table below contains information regarding the current members of the Board of Directors and executive officers. The ages of individuals are provided as of the date of this prospectus:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Christopher J. Schaber, PhD	50	Chairman of the Board, Chief Executive Officer and President
Keith L. Brownlie, CPA	64	Director
Marco M. Brughera, DVM	61	Director
Gregg A. Lapointe, CPA	58	Director
Robert J. Rubin, MD	70	Director
Jerome B. Zeldis, MD, PhD	66	Director
Oreola Donini, PhD	44	Chief Scientific Officer and Senior Vice President
Karen R. Krumeich	63	Chief Financial Officer and Senior Vice President
Richard Straube, MD	65	Chief Medical Officer and Senior Vice President

Christopher J. Schaber, PhD has over 26 years of experience in the pharmaceutical and biotechnology industry. Dr. Schaber has been our President and Chief Executive Officer and a director since August 2006. He was appointed Chairman of the Board on October 8, 2009. He also serves on the board of directors of the Biotechnology Council of New Jersey (“BioNJ”) since January 2009 and the Alliance for Biosecurity since October 2014, and has been a member of the corporate councils of both the National Organization for Rare Diseases (“NORD”) and the American Society for Blood and Marrow Transplantation (“ASBMT”) since October 2009 and July 2009, respectively. Prior to joining us, Dr. Schaber served from 1998 to 2006 as Executive Vice President and Chief Operating Officer of Discovery Laboratories, Inc., where he was responsible for overall pipeline development and key areas of commercial operations, including regulatory affairs, quality control and assurance, manufacturing and distribution, pre-clinical and clinical research, and medical affairs, as well as coordination of commercial launch preparation activities. From 1996 to 1998, Dr. Schaber was a co-founder of Acute Therapeutics, Inc., and served as its Vice President of Regulatory Compliance and Drug Development. From 1994 to 1996, Dr. Schaber was employed by Ohmeda PPD, Inc., as Worldwide Director of Regulatory Affairs and Operations. From 1989 to 1994, Dr. Schaber held a variety of regulatory, development and operations positions with The Liposome Company, Inc., and Elkins-Sinn Inc., a division of Wyeth-Ayerst Laboratories. Dr. Schaber received his BA degree from Western Maryland College, his MS degree in Pharmaceutics from Temple University School of Pharmacy and his PhD degree in Pharmaceutical Sciences from the Union Graduate School. Dr. Schaber was selected to serve as a member of our Board of Directors because of his extensive experience in drug development and pharmaceutical operations, including his experience as an executive senior officer with our Company and Discovery Laboratories, Inc., and as a member of the board of directors of BioNJ; because of his proven ability to raise funds and provide access to capital; and because of his advanced degrees in science and business.

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



experience as an audit partner for numerous public companies and as a director of publicly traded specialty pharmaceutical and biotechnology companies.

Marco M. Brughera, DVM joined the Board of Directors in October 2013. He is the Global Head of the Rare Disease Business Unit for Sigma Tau Finanziaria S.p.A. Group. He currently serves as President in Sigma-Tau Pharmaceuticals, Inc. and in Sigma-Tau Research Switzerland S.A. and as Chief Executive Officer in Sigma-Tau Rare

Disease Ltd. From December 2011 through January 2014, Dr. Brughera served on the Board of Directors of Gentium S.p.A., a publicly traded biopharmaceutical company. From January 2011 through October 2012, Dr. Brughera held several other positions with the Sigma-Tau Group, including Corporate Research and Development Managing Director of Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.. From 2004 to 2010, Dr. Brughera served as the Vice President of Preclinical Development at Nerviano Medical Sciences S.r.l. (“NMS Group”), a pharmaceutical oncology-focused integrated discovery and development company. He also served as the Managing Director at Accelera, S.r.l., an independent contract research organization affiliated with the NMS Group. From 1999 to 2004, Dr. Brughera held several senior level positions in the areas of discovery and development toxicology with Pharmacia Corporation and Pfizer, Inc. Prior to 1999, he held various positions at Pharmacia & Upjohn Company, Inc., and Farmitalia Carlo Erba S.p.A., an Italian pharmaceutical company. Dr. Brughera earned his degree in veterinary medicine from the University of Milan and is a European Registered Toxicologist. Dr. Brughera was selected to serve as a member of our Board of Directors because of his background in the areas of drug discovery and development and his experience as an executive officer and a director in the pharmaceutical industry.

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

Robert J. Rubin, MD has been a director since October 2009. Dr. Rubin was a clinical professor of medicine at Georgetown University from 1995 until 2012 when he was appointed a Distinguished Professor of Medicine. From 1987 to 2001, he was president of the Lewin Group (purchased by Quintiles Transnational Corp. in 1996), an international health policy and management consulting firm. From 1994 to 1996, Dr. Rubin served as Medical Director of ValueRx, a pharmaceutical benefits company. From 1992 to 1996, Dr. Rubin served as President of Lewin-VHI, a health care consulting company. From 1987 to 1992, he served as President of Lewin-ICF, a health care consulting company. From 1984 to 1987, Dr. Rubin served as a principal of ICF, Inc., a health care consulting company. From 1981 to 1984, Dr. Rubin served as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services and as an Assistant Surgeon General in the United States Public Health Service. Dr. Rubin has served on the Board of BioTelemetry, Inc. (formerly known as CardioNet, Inc.) since 2007. He is a board certified nephrologist and internist. Dr. Rubin received an undergraduate degree in Political Science from Williams College and his medical degree from Cornell University Medical College. Dr. Rubin was selected to serve as a member of our Board of Directors because of his vast experience in the health care industry, including his experience as a nephrologist, internist, clinical professor of medicine and Assistant Surgeon General, and his business experience in the pharmaceutical industry.

Jerome B. Zeldis, MD, PhD has been a director since June 2011. Dr. Zeldis is currently Chief Executive Officer of Celgene Global Health and Chief Medical Officer of Celgene Corporation, a publicly traded, fully integrated biopharmaceutical company, where he has been employed since 1997. From September 1994 to February 1997, Dr. Zeldis worked at Sandoz Research Institute and the Janssen Research Institute in both clinical research and medical

development. He has been a board member of several biotechnology companies and is currently on the boards of the NJ Chapter of the Arthritis Foundation, the Castleman's Disease Organization, PTC Therapeutics, Inc. and Alliqua, Inc. Additionally, he has served as Assistant Professor of Medicine at the Harvard Medical School (from July 1987 to September 1988), Associate Professor of Medicine at University of California, Davis from (September 1988 to September 1994), Clinical Associate Professor of Medicine at Cornell Medical School (January 1995 to December 2003) and Professor of Clinical Medicine at the Robert Wood Johnson Medical School (July 1998 to June 2010). Dr. Zeldis

received a BA and an MS from Brown University, and an MD, and a PhD in Molecular Biophysics and Biochemistry from Yale University. Dr. Zeldis trained in Internal Medicine at the UCLA Center for the Health Sciences and in Gastroenterology at the Massachusetts General Hospital and Harvard Medical School. Dr. Zeldis was selected to serve as a member of our Board of Directors because of his experience as an executive officer of a publicly traded biopharmaceutical company and in clinical research and medical development, and his experience in the health care industry, including his experience as an internist, gastroenterologist and professor of medicine.

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

Karen R. Krumeich is currently our Chief Financial Officer and Senior Vice President, a position she has held since June 16, 2016. From September 2013 to June 2016, Ms. Krumeich has served as a consultant providing finance, investor relations, business development and public relations services to our company and other healthcare companies. From May 2011 to May 2013, she worked as Vice President of Finance of Cerecor, Inc., a publicly-traded biopharmaceutical company, where she was responsible for equity financings, corporate administrative functions, and investor relations. In addition to these positions, Ms. Krumeich was a healthcare consultant partner with Tatum, LLC, a national consulting firm, where she served as Interim Chief Financial Officer of several private and public life science and technology companies, and was Chief Financial Officer of Mela Sciences, Inc., a publicly-traded medical device company. Prior to these positions, she held positions of increasing responsibility with several healthcare companies, including Bristol-Myers Squibb Company, a public pharmaceutical company, where she was Director of Health Systems and as Vice President of Finance for a national pharmacy provider. Ms. Krumeich began her career as a pharmacist and transitioned into finance after successfully completing the CPA exam. Ms. Krumeich earned a B.Sc. in Pharmacy from the University of Toledo, Ohio and completed her post graduate work in accounting and finance at Cleveland State University while pursuing her career as a pharmacist.

Richard Straube, MD has been with our company since January 2014 and is currently our Senior Vice President and Chief Medical Officer. Dr. Straube is a board-certified pediatrician with 35 years' experience in both academia and industry, including clinical research experience in host-response modulation. From 2009 until joining our company, he was Chief Medical Officer of Stealth Peptides Incorporated, a privately-held, clinical stage, biopharmaceutical company. Prior to joining the Company, Dr. Straube served from 1988 to 1993 in various capacities, including most recently as Senior Director, Infectious Diseases and Immunology, Clinical Research, for Centocor, Inc., a privately-held biopharmaceutical company focused on developing monoclonal antibody-based diagnostics. While at Centocor, Inc., Dr. Straube was responsible for the initial anti-cytokine and anti-endotoxin programs targeted at

ameliorating inappropriate host responses to infectious and immunologic challenges. Programs that he managed at Centocor, Inc. include assessments of immunomodulation using monoclonal removal of inciting molecular triggers, removal of internal immune-messengers, augmentation of normal host defenses, and maintenance of normal sub-cellular function in the face of injury. From 1993 to 1995, Dr. Straube was Director of Medical Affairs at T-cell Sciences, Inc., a privately-held biotechnology company. From 1995 to 1997, he was Director of Clinical Investigations of the Pharmaceutical Products Division of Ohmeda Corp., a privately-held biopharmaceutical company. He served

from 1998 to 2007 as Executive Vice President of Research and Development and Chief Scientific Officer at INO Therapeutics LLC, a privately-held biotherapeutics company, where he was responsible for the clinical trials and subsequent approval of inhaled nitric oxide for the treatment of persistent pulmonary hypertension of the newborn. From 2007 to 2009, Dr. Straube was the Chief Medical Officer at Critical Biologics Corporation, a privately-held biotechnology company. Dr. Straube received his medical degree and residency training at the University of Chicago, completed a joint adult and pediatric infectious diseases fellowship at the University of California, San Diego (“UCSD”), and as a Milbank Scholar completed training in clinical trial design at the London School of Hygiene and Tropical Medicine. While on the faculty at the UCSD Medical Center, his research focused on interventional studies for serious viral infections.

#### Board Leadership Structure

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

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

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

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

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

#### Director Independence

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

Committees of the Board of Directors

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

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

— Committee Chair

— Member

Audit Committee

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

Compensation Committee

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

Nominating and Corporate Governance Committee

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



such term is defined by the applicable NASDAQ listing standards.

#### Code of Ethics

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

implicit waiver, from a provision of the code to our chief executive officer, chief financial officer or chief accounting officer, we will disclose the nature of such amendment or waiver in a Current Report on Form 8-K.

#### Diversity Considerations in Identifying Director Nominees

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

#### Compensation Committee Interlocks and Insider Participation

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

#### Stock Ownership Policy

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

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

## EXECUTIVE COMPENSATION

## Summary Compensation Table

The following table contains information concerning the compensation paid during each of the two years ended December 31, 2015 and December 31, 2014 to our Chief Executive Officer and each of the two other most highly compensated executive officers during 2015 (collectively, the “Named Executive Officers”).

Name	Position	Year	Salary	Bonus	Option Awards	All Other Compensation	Total
Christopher J. Schaber <sup>1</sup>	CEO & President	2015	\$ 424,360	\$ 101,846	\$ 158,200	\$ 36,201	\$ 720,607
		2014	\$ 412,000	\$ 115,000	\$ 150,000	\$ 29,580	\$ 706,580
Joseph M. Warusz <sup>2</sup>	Former VP & Acting CFO	2015	\$ 196,730	\$ 38,362	\$ 62,150	\$ 24,676	\$ 321,918
		2014	\$ 191,000	\$ 41,000	\$ 67,500	\$ 21,197	\$ 320,697
Richard C. Straube <sup>3</sup>	CMO & Senior VP	2015	\$ 309,000	\$ 58,401	\$ 79,100	\$ 25,656	\$ 472,157
		2014	\$ 300,000	\$ 62,000	\$ 276,000	\$ 21,328	\$ 659,328

1 Dr. Schaber deferred the payment of his 2015 bonus of \$101,846 until January 15, 2016. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

2 Mr. Warusz deferred the payment of his 2015 bonus of \$38,362 until January 15, 2016. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company. On June 30, 2016, Mr. Warusz retired from the Company.

3 Dr. Straube joined the Company on January 1, 2014. He deferred the payment of his 2015 bonus of \$58,401 until January 15, 2016. Option award figures include the value of common stock option awards at grant date as calculated under FASB ASC 718. Other compensation represents health insurance costs paid by the Company.

## Employment and Severance Agreements

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

In the event of his death during the term of the agreement, all of his unvested options shall immediately vest and remain exercisable for the remainder of their term and become the property of Dr. Schaber's immediate family.

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

On June 22, 2011, the Compensation Committee eliminated his fixed minimum annual bonus payable and revised it to an annual targeted bonus of 40% of his annual base salary. On December 4, 2013, the Compensation Committee approved an increase in salary for Dr. Schaber to \$412,000. On December 4, 2014, the Compensation Committee approved an increase in salary for Dr. Schaber to \$424,360. On December 10, 2015, the Compensation Committee approved an increase in salary for Dr. Schaber to \$434,969.

In May 2011, we entered into a one-year employment agreement with Mr. Joseph M. Warusz, our Acting Chief Financial Officer, Vice President Finance and Chief Accounting Officer. Pursuant to the agreement, we have agreed to pay Mr. Warusz \$175,000 per year and a targeted annual bonus of 30% of base salary. We also agreed to issue him options to purchase 4,000 shares of our common stock with one-third immediately vesting and the remainder vesting over three years. Mr. Warusz's employment agreement automatically renews each year, unless otherwise terminated, and was automatically renewed each year since execution, until Mr. Warusz retired from the Company effective June 30, 2016. In connection with his retirement, we agreed to provide Mr. Warusz three months of salary and three months of health insurance benefits and to accelerate the vesting and extend the exercise period of certain options. On December 6, 2012, the Compensation Committee approved an increase in the targeted annual bonus to 35%. On December 4, 2013, the Compensation Committee approved an increase in salary for Mr. Warusz to \$191,000. On December 4, 2014, the Compensation Committee approved an increase in salary for Mr. Warusz to \$196,730. On December 10, 2015, the Compensation Committee approved an increase in salary for Mr. Warusz to \$201,648.

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

In June 2016, we entered into a one-year employment agreement with Karen R. Krumeich, our Chief Financial Officer and Senior Vice President. Pursuant to the agreement, we have agreed to pay Ms. Krumeich \$222,000 per year and a targeted annual bonus of 30% of base salary. We also agreed to issue her options to purchase 10,000 shares of our common stock with one-fourth immediately vesting and the remainder vesting over three years. Ms. Krumeich's employment agreement automatically renews each year, unless otherwise terminated. Upon termination without "Just Cause", as defined in Ms. Krumeich's employment agreement, we would pay Ms. Krumeich three months of severance, accrued bonuses and vacation, and health insurance benefits. No unvested options vest beyond the termination date.

#### Outstanding Equity Awards at Fiscal Year-End

The following table contains information concerning unexercised options, stock that has not vested, and equity incentive plan awards for the Named Executive Officers outstanding at December 31, 2015, as adjusted for the reverse stock split of one-for-ten effective October 7, 2016. We have never issued Stock Appreciation Rights.

Name	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable	Unearned		
Christopher J. Schaber	12,500	—	—	\$ 54.00	8/28/16
	4,500	—	—	\$ 94.00	8/9/2017

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14,000	—	—	\$	12.00	12/17/2018
11,000	—	—	\$	46.40	6/30/2020
11,219	—	—	\$	6.40	11/30/2021
13,000	—	2,500	\$	6.80	12/04/2022
7,500	2,500	5,000	\$	20.10	12/04/2023
5,000	5,000	10,500	\$	15.00	12/04/2024
3,500	10,500	2,500	\$	11.30	12/30/2025

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Name	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)			Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable	Unexercised	Unexercised	Unexercised		
Richard C. Straube	6,875	3,125	3,125			\$ 20.10	1/06/2024
	2,500	2,500	2,500			\$ 15.00	12/04/2024
	1,750	5,250	5,250			\$ 11.30	12/30/2025
Joseph M. Warusz	4,000	—	—			\$ 41.00	6/30/2021
	2,531	—	—			\$ 6.40	6/30/2021
	5,500	—	—			\$ 6.80	6/30/2021
	3,376	1,125	1,125			\$ 20.10	6/30/2021
	2,251	2,250	2,250			\$ 15.00	6/30/2021
	1,375	4,125	4,125			\$ 11.30	6/30/2021

## Compensation of Directors

The following table contains information concerning the compensation of the non-employee directors during the fiscal year ended December 31, 2015.

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

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

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

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

We are party to a common stock purchase agreement with Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau Pharmaceuticals”), a corporation of which Paolo Cavazza, who beneficially owns 5% or more of the shares of our outstanding common stock, indirectly owns 37.2%. The agreement provides that Sigma-Tau Pharmaceuticals has the right to require that we register its shares under the Securities Act of 1933 (the “Securities Act”) for sale to the public, on not more than one occasion during any twelve-month rolling period, and not more than two occasions in the aggregate. We must pay all expenses incurred in connection with the exercise of these demand registration rights. Additionally, the agreement required us to use our best efforts to secure the election of a Sigma-Tau Pharmaceuticals’ designee to our Board of Directors as long as Sigma-Tau Pharmaceuticals beneficially owned at least 10% of our issued and outstanding shares of common stock. As of the date of this prospectus, Sigma-Tau Pharmaceuticals beneficially owned 8% of our outstanding common stock, and our obligation with respect to the election of a Sigma-Tau Pharmaceuticals designee to our Board of Directors has expired.

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

We are party to a stock issuance agreement with Intrexon Corporation (“Intrexon”), a corporation of which Randall J. Kirk, who beneficially owns 5% or more of the shares of our outstanding common stock, serves as the Chairman and Chief Executive Officer. Under the agreement, Intrexon has piggyback registration rights, which means that it has the right to include its shares in any registration that we effect under the Securities Act, subject to specified exceptions. We must pay all expenses, except any broker or similar commissions, incurred in connection with these piggyback registration rights.

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

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

In our June 2013 public offering, we issued warrants that contained provisions protecting holders from a decline in the issue price of our common stock (or “down-round” provision) and contained net settlement provisions. As a result, we accounted for these warrants as liabilities instead of equity instruments. During November 2016, we entered into amendments with the holders of those warrants pursuant to which we agreed to reduce the exercise price (after giving effect to the one-for-ten reverse stock split effective October 7, 2016) from \$5.10 per share to \$0.80 per share and permit those warrants to be exercised on a “cashless exercise” basis, and we eliminated the “down round” provision of those warrants not immediately exercised. As a result of the amendments, the warrant liability was remeasured as of the date of the modification, which resulted in an approximate \$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 250,000 shares were held by NRM VII Holdings I, LLC, an entity the manager of which is indirectly controlled by Mr. Kirk.

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

## SECURITY OWNERSHIP OF MANAGEMENT AND OTHER BENEFICIAL OWNERS

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

Name of Beneficial Owner	Shares of Common Stock		Percent of Class
	Beneficially Owned**		
Randall J. Kirk <sup>(1)</sup>	686,783	16.96	%
NRM VII Holdings I, LLC <sup>(1)</sup>	583,334	14.40	%
Paolo Cavazza <sup>(2)</sup>	337,998	8.79	%
Sigma-Tau Pharmaceuticals, Inc. <sup>(2)</sup>	306,847	8.00	%
SciClone Pharmaceuticals, Inc. <sup>(3)</sup>	352,942	9.29	%
Christopher J. Schaber <sup>(4)</sup>	90,505	2.33	%
Keith Brownlie <sup>(5)</sup>	14,047		*
Marco Brughera <sup>(6)</sup>	6,885		*
Gregg A. Lapointe <sup>(7)</sup>	17,676		*
Robert J. Rubin <sup>(8)</sup>	13,642		*
Jerry Zeldis <sup>(9)</sup>	15,130		*
Richard Straube <sup>(10)</sup>	16,631		*
Oreola Donini <sup>(11)</sup>	16,756		*
Karen R. Krumeich <sup>(12)</sup>	5,050		*
All directors and executive officers as a group (9 persons)		4.95	%

(1) On June 26, 2013, Randal J. Kirk, on his own behalf and on behalf of Third Security, LLC, NRM VII Holdings I, LLC and Intrexon, filed Amendment No. 1 to Schedule 13D with the SEC, which amends the Schedule 13D filed May 9, 2013 with the SEC (as amended, "Schedule 13D"). The Schedule 13D states that Mr. Kirk is Senior Managing Director of, and controls, Third Security, LLC, which is the Manager of an affiliate that manages NRM VII Holdings I, LLC, and that Mr. Kirk serves as the Chairman and Chief Executive Officer of Intrexon. The Schedule 13D indicates that (a) Mr. Kirk, Third Security, LLC and NRM VII Holdings I, LLC have sole voting and dispositive power with respect to 333,333 shares of Common Stock and warrants to purchase 250,000 shares of Common Stock exercisable within 60 days of the date of this prospectus held by NRM VII Holdings I, LLC, and (b) Mr. Kirk and Intrexon have shared voting and dispositive power with respect to 103,449 shares of Common Stock held by Intrexon. The address of the principal business office of Mr. Kirk is 2875 South Ocean Boulevard, Suite 214, Palm Beach, Florida 33480. The address of the principal business office of NRM VII Holdings I, LLC is c/o Third Security, LLC, 1881 Grove Avenue, Redford, Virginia 24141. The address of the principal business office of Intrexon is 20358 Seneca Meadows Parkway, Germantown, Maryland 20876.

(2) On May 16, 2013, Paolo Cavazza, on his own behalf and on behalf of Sigma Tau Finanziaria S.p.A., Sigma-Tau International S.A., Sigma-Tau America S.A. and Sigma-Tau Pharmaceuticals filed Amendment No. 4 to Schedule 13D with the SEC, which amends the Schedule 13D filed with the SEC on February 20, 2009 as amended by Amendment No. 1 filed with the SEC on October 2, 2009, Amendment No. 2 filed with the SEC on June 28, 2010 and Amendment No. 3 filed with the SEC on January 2, 2013 (the "Schedule 13D"). The Schedule 13D indicates that (a) Mr. Cavazza has sole voting and dispositive power with respect to (i) 5,954 shares held by Mr. Paolo Cavazza and (ii) 16,415 shares of common stock and warrants to purchase 8,781 shares held by SINAF SA, and (b) Mr. Cavazza, Sigma Tau Finanziaria S.p.A., Sigma-Tau International S.A., Sigma-Tau America S.A. and Sigma-Tau

Pharmaceuticals have shared voting and dispositive power with respect to 271,140 shares of common stock and warrants to purchase 35,707 shares of common stock exercisable within 60 days of the date of this prospectus held by Sigma-Tau Pharmaceuticals. Sigma-Tau Pharmaceuticals is a direct wholly-owned subsidiary of Sigma Tau Finanziaria S.p.A. Mr. Paolo Cavazza directly and indirectly owns 37.2% of Sigma Tau Finanziaria S.p.A. SINAF SA is a wholly owned subsidiary of Aptafin S.p.A., which is owned by Mr. Paolo Cavazza and members of his family. Mr. Paolo Cavazza's address is Via Tesserte, 10, Lugano, Switzerland. The business address of Sigma Tau Finanziaria S.p.A. is Via Sudafrica, 20, Rome, Italy 00144. The business address of Sigma-Tau Pharmaceuticals is 9841 Washingtonian Boulevard, Suite 500, Gaithersburg, Maryland 20878.

- (3) On September 19, 2016, SciClone Pharmaceuticals, Inc., filed a Schedule 13G with the SEC (the “Schedule 13G”). The Schedule 13G indicates that SciClone Pharmaceuticals, Inc. has sole voting and dispositive power with respect to the 352,942 shares held by SciClone Pharmaceuticals International China Holding Ltd. SciClone Pharmaceuticals International China Holding Ltd. is an indirect wholly-owned subsidiary of SciClone Pharmaceuticals, Inc.
- (4) Includes 9,291 shares of common stock owned by Dr. Schaber, options to purchase 80,719 shares of common stock exercisable within 60 days of the date of this prospectus, and warrants to purchase 496 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Schaber is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540
- (5) Includes 5,000 shares of common stock and options to purchase 9,047 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Mr. Brownlie is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (6) Includes 750 shares of common stock and options to purchase 6,135 shares of common stock owned by Dr. Brughera exercisable within 60 days of the date of this prospectus. The address of Dr. Brughera is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (7) Includes 7,379 shares of common stock and options to purchase 10,298 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Mr. Lapointe is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (8) Includes 1,220 shares of common stock and options to purchase 12,422 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Rubin is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (9) Includes 6,917 shares of common stock and options to purchase 8,213 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Zeldis is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (10) Includes options to purchase 16,631 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Straube is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (11) Includes options to purchase 11,756 shares of common stock owned by Dr. Donini exercisable within 60 days of the date of this prospectus and warrants to purchase 5,000 shares of common stock exercisable within 60 days of the date of this prospectus. The address of Dr. Donini is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.
- (12) Includes 1,300 shares of common stock and options to purchase 3,750 shares of common stock owned by Ms. Krumeich exercisable within 60 days of the date of this prospectus. The address of Ms. Krumeich is c/o Soligenix, 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540.

\* Indicates less than 1%.

\*\* Beneficial ownership is determined in accordance with the rules of the SEC. Shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of the date of this prospectus are deemed outstanding for computing the percentage ownership of the stockholder holding the options or warrants, but are not deemed outstanding for computing the percentage ownership of any other stockholder. Percentage of ownership is based on 3,800,032 shares of common stock outstanding as of the date of this prospectus.



## UNDERWRITING

Aegis Capital Corp. is acting as the sole book-running manager of the offering and as representative of the underwriters, or the Representative. We have entered into an underwriting agreement, dated \_\_\_\_\_, 2016, with the Representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally and not jointly agreed to purchase from us, at the public offering price per share less the underwriting discounts set forth on the cover page of this prospectus and as set forth below, the number of shares of common stock and warrants listed next to its name in the following table:

Underwriter	Number of Shares	Number of Warrants
Aegis Capital Corp.		
Maxim Group LLC		
Total		

The underwriters are committed to purchase all the shares of common stock and warrants offered by us other than those covered by the over-allotment option to purchase additional shares and warrants described below, if they purchase any shares and warrants. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares and warrants, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of \_\_\_\_\_ additional shares and/or \_\_\_\_\_ warrants (15% of the shares and/or warrants sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase shares and/or warrants covered by the option at the public offering price per share that appears on the cover page of this prospectus, less the 6% underwriting discount. If this option is exercised in full, the total price to the public will be \$ \_\_\_\_\_ and the total net proceeds, before expenses, to us will be \$ \_\_\_\_\_.

Discount. The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Per Warrant	Total Without Over-allotment Option	Total With Over-allotment Option
Public offering price	\$	\$	\$	\$
Underwriting discount (6%) <sup>(1)</sup>				
Underwriting discount (3%) <sup>(1)</sup>				
Non-accountable expense allowance (1%) <sup>(2)</sup>				
Proceeds, before expenses, to us	\$	\$	\$	\$

(1) We and the underwriters have agreed to a commission of 3% on securities issued and sold to certain investors. In addition, no commission will be paid by us for securities issued and sold to members of our Board of Directors and/or our executive officers.

(2) The non-accountable expense allowance is equal to 1% of the amount of the public offering.

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The underwriters propose to offer the shares and warrants to the public at the public offering price per share and per warrant set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares and warrants to other securities dealers at such price less a concession of \$ per share and warrant. If all of the shares and warrants offered by us are not sold at the public offering price, the underwriters may change the offering price and other selling terms by means of a supplement to this prospectus.

We have paid an expense deposit of \$20,000 to the Representative, which will be applied against the accountable expenses that will be paid by us to the Representative in connection with this offering. The \$20,000 expense deposit will be returned to us to the extent not actually incurred. The underwriting agreement also provides that in the event the offering is terminated, the \$20,000 expense deposit paid to the Representative will be returned to us to the extent that offering expenses are not actually incurred by the Representative.

We have also agreed to pay the Representative's out-of-pocket accountable expenses relating to the offering, including (a) all fees, expenses and disbursements relating to background checks of our officers and directors in an amount not to exceed \$3,000 per individual and \$15,000 in the aggregate; (b) all filing fees incurred in clearing this offering with FINRA; (c) all fees, expenses and disbursements relating to the registration, qualification or exemption of securities offered under the securities laws of foreign jurisdictions designated by the underwriters; (d) all fees, expenses and disbursements relating to the registration, qualification or exemption of the securities in the offering under the "blue sky laws (including all filing and registration fees and reasonable fees of "blue sky" counsel up to \$5,000; (e) the fees and expenses of the underwriters' legal counsel not to exceed \$50,000; (f) \$29,500 for the underwriters' use of Ipreo's book-building, prospectus tracking and compliance software for this offering; (g) up to \$20,000 of the Representative's actual accountable road show expenses for the offering; and (h) the cost of preparation of bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones in such quantities as the Representative may reasonable request in an amount not to exceed \$5,000.

We estimate that the total expenses of the offering payable by us, excluding underwriting discounts and commissions, will be approximately \$375,000, not including the non-accountable expense allowance.

**Discretionary Accounts.** The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

**Lock-Up Agreements.** Pursuant to certain "lock-up" agreements, we, our executive officers and directors, and holders of 5% or more of our outstanding shares of common stock on a fully diluted basis (including shares underlying options, warrants and convertible securities) have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the Representative, for a period of 90 days from the date of effectiveness of the offering. Notwithstanding the foregoing, we will, at all times, be permitted to file any registration statement with the SEC relating to the resale of shares of our capital stock by Hy Biopharma, Inc., Yeda Research and Development Company, Ltd. And New York University in order to satisfy our obligations under that certain registration rights agreement with Hy Biopharma, Inc., dated September 3, 2014.

**Representative's Warrants.** We have agreed to issue to the Representative warrants to purchase up to a total of \_\_\_\_\_ shares of common stock (2% of the shares of common stock sold in this offering, but excluding any shares sold to members of our Board and/or our executive officers). The warrants will be exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the offering, which period shall not extend further than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(G)(i). The warrants are exercisable at a per share price equal to \$ per share, or 125% of the public offering price per share in the offering. The warrants have been deemed compensation by FINRA and are therefore



subject to a 180 day lock-up pursuant to Rule 5110(g)(1) of FINRA. The Representative (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the date of effectiveness. In addition, the warrants provide for registration rights upon request, in certain cases. The piggyback registration right provided will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(G)(v). We will bear all fees and expenses attendant to registering the securities issuable

on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

**Electronic Offer, Sale and Distribution of Securities.** A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The Representative may agree to allocate a number of shares and warrants to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

**Determination of the Initial Public Offering Price.** The public offering price was determined through negotiations between us and the Representative of the underwriters. In addition to prevailing market conditions, the factors considered in determining the public offering price included the following:

- the information included in this prospectus and otherwise available to the Representative;
- the valuation multiples of publicly traded companies that the Representative believe to be comparable to us;
- our financial information;
- our prospects and the history and the prospectus of the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for our common stock and our warrants may not develop. It is also possible that, after the offering, the shares and warrants will not trade in the public market at or above the initial public offering price.

**Stabilization.** In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.
- Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment

option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through

exercise of the over-allotment option. If the underwriters sell more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

- Penalty bids permit the Representative to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be effected on The NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive market making. In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on The NASDAQ Capital Market or in the over-the-counter market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the securities and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships. Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees. However, except as disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

#### Offer restrictions outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

#### Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth

in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer for the offeree under this prospectus.

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## China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

## European Economic Area — Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- (a) to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than € 43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than € 50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- (c) to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

## France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account,

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as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

## Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the “Prospectus Regulations”). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

## Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority, or the ISA, nor have such securities been registered for sale in Israel. The shares and warrants may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

## Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa, “CONSOB” pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 (“Decree No. 58”), other than:

- to Italian qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 (“Regulation no. 11971”) as amended (“Qualified Investors”); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

## Japan



The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the “FIEL”) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder).

Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

#### Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are “qualified investors” (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

#### Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are “qualified investors” (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

#### Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority.

This document is personal to the recipient only and not for general circulation in Switzerland.

#### United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates.

This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to “qualified investors” (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA.

This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together “relevant persons”). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

## DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 10,350,000 shares of capital stock, of which 10,000,000 shares are common stock, par value \$0.001 per share, 230,000 shares are undesignated preferred stock, 10,000 shares are Series B Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding), 10,000 shares are Series C Convertible Preferred Stock, par value \$0.05 per share (none of which are currently outstanding) and 100,000 shares are Series A Junior Participating Preferred Stock, par value \$0.001 per share (which are available for issuance under our shareholder rights plan). As of the date of this prospectus there were issued and outstanding 3,800,032 shares of common stock, options to purchase 299,752 shares of common stock and warrants to purchase 450,170 shares of common stock.

On October 7, 2016, we effected a reverse stock split at a ratio of one-for-ten of all the issued and outstanding shares of our common stock. We also reduced our authorized shares of common stock from 100,000,000 to 10,000,000.

### Common Stock

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

### Preferred Stock

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

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

### Series B Preferred Stock

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

### Voting

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

together with the holders of common stock as a single class.

#### Dividends

The holders of the Series B Preferred Stock are entitled to a dividend of 8% per annum, payable annually in shares of Series B Preferred Stock. In addition, when and if the Board of Directors shall declare a dividend payable

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with respect to the then outstanding shares of common stock, the holders of the Series B Preferred Stock are entitled to the amount of dividends per share as would be payable on the largest number of whole shares of common stock into which each share of Series B Preferred Stock could then be converted.

#### Conversion

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

#### Liquidation

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

#### Redemption

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

#### Junior Preferred Stock

#### Voting

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

#### Dividends

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

#### Liquidation

Upon any liquidation, dissolution or winding up, no distribution may be made to the holders of shares of stock ranking junior to the Junior Preferred Stock unless the holders of the Junior Preferred Stock have received the greater of (i) \$37.00 per one one-thousandth share plus an amount equal to accrued and unpaid dividends and distributions thereon, and (ii) an amount equal to 10,000 times the aggregate amount to be distributed per share to holders of common stock.

Further, no distribution may be made to the holders of stock ranking on a parity upon liquidation, dissolution or winding up with the Junior Preferred Stock, unless distributions are made ratably on the Junior Preferred Stock and all other shares of such parity stock in proportion to the total amounts to which the holders of the Junior Preferred Stock are entitled above and to which the holders of such parity shares are entitled.



## Offering Warrants

The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of the warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of warrant.

**Exercisability.** The warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

**Cashless Exercise.** In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. In no event shall we be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of common stock underlying the warrants.

**Exercise Price.** The initial exercise price per share of common stock purchasable upon exercise of the warrants is 125% of the public offering price of the common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

**Certain Adjustments.** The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock.

**Transferability.** Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

**Warrant Agent and Exchange Listing.** The warrants will be issued in registered form under a warrant agency agreement between American Stock Transfer & Trust Company, LLC, as warrant agent and us.

**Fundamental Transaction.** If, at any time while the warrants are outstanding, (1) we consolidate or merge with or into another corporation and we are not the surviving corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our shares of common stock are permitted to sell, tender or exchange their shares of common stock for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of common stock, (4) we effect any reclassification or recapitalization of our shares of common stock or any compulsory share exchange pursuant to which our shares of common stock are converted into or exchanged for other securities, cash or property, or (5) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding shares of common stock, each, a "Fundamental Transaction," then upon any subsequent exercise of the warrants, the holders thereof will have the right to

receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction.

**Rights as a Stockholder.** Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

## Representative's Warrants

Please see "Underwriting — Representative's Warrants" for a description of the warrants we have agreed to issue to the representative of the underwriters in this offering, subject to the completion of the offering. We expect to enter into a warrant agreement in respect of the Representative's Warrants prior to the closing of this offering.

## Shareholder Rights Plan

On June 22, 2007, our board of directors adopted a shareholder rights plan for our company and in connection therewith declared a dividend of one preferred share purchase right for each outstanding share of common stock. Each Right entitles the registered holder to purchase one one-thousandth of a share of our Junior Preferred Stock at a price of \$37.00 per one one-thousandth of a share, subject to certain adjustments. Initially, the rights are not exercisable, but become exercisable upon the earlier of (i) 10 days following a public announcement that a person or group of affiliated or associated persons, with certain exceptions, has acquired beneficial ownership of 15% or more of the then outstanding common stock or (ii) 10 business days following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of such outstanding common stock.

Our board may redeem all of the rights for \$0.10 per right at any time before the earlier of (i) the time the rights become exercisable or (ii) July 1, 2017, the date the rights expire.

## Anti-Takeover Provisions

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

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

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

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

## Outstanding Warrants

On June 25, 2013, we consummated a public offering of an aggregate of 677,400 shares of common stock, together with warrants to purchase up to 508,050 shares of common stock. In connection with the offering, we also issued the

placement agent a warrant to purchase up to 33,609 shares of common stock. If the registration statement covering the shares issuable upon exercise of the warrants issued to the investors is no longer effective, such warrants may be exercised on a “cashless” basis. The placement agent warrant has terms substantially similar to the warrants issued to the investors but provide for a cashless exercise feature without regard to status of the registration statement covering the shares issuable upon exercise of the warrants. We refer to the warrants issued to the investors and the placement agent in connection with the offering as the “2013 Warrants.”

The 2013 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 outstanding 2013 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 the 2013 Warrants to be exercised on a “cashless exercise” basis, and we eliminated the “down round” provision of the outstanding 2013 Warrants. 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 the 2013 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.

As a result of exercises, 261,250 shares of common stock remain issuable upon the exercise of the 2013 Warrants as of the date of this prospectus. The 2013 Warrants expire in June 2018.

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

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

As of the date of this prospectus, 110,932 shares of common stock remain issuable upon the exercise of the 2014 Warrants, which expire in 2019.

As of the date of this prospectus, we also had outstanding warrants, other than the 2013 Warrants and the 2014 Warrants, to purchase 77,988 shares of common stock, all of which are exercisable at a weighted average exercise price of approximately \$5.67 per share.

#### Delaware Anti-Takeover Statute

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

- prior to the date of the transaction, our Board of Directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, calculated as provided under Section 203; or
- at or subsequent to the date of the transaction, the business combination is approved by our Board of Directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates,

owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our Board of Directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

## Transfer Agent

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

## Listing

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.

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

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

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

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

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

## LEGAL MATTERS

The validity of the shares of our common stock and warrants offered hereby will be passed upon by the law firm of Duane Morris LLP, Miami, Florida. Certain legal matters in connection with this offering will be passed upon for the underwriters by Gracin & Marlow, LLP, New York, New York.

## EXPERTS

The consolidated balance sheets of Soligenix, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in shareholders' deficiency, and cash flows for each of the years then ended, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is included herein. Such financial statements have been included herein in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

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

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

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

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

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

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" certain information that we will file with it which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of this offering, however, we will not incorporate by reference any documents or portions thereof that are not deemed "filed" with the SEC, or any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K.

Any statement contained in a document incorporated by reference into this Registration Statement will be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained in this document, any Registration Statement supplement or any other subsequently filed document that is incorporated by reference into this Registration Statement modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement.



We make available through our website, free of charge, copies of these reports as soon as reasonably practicable after we electronically file or furnish them to the SEC. Our website is located at <http://www.soligenix.com>. You can also request copies of such documents, free of charge, by contacting the company at (609) 538-8200 or sending an email to [info@soligenix.com](mailto:info@soligenix.com).

SOLIGENIX, INC. AND SUBSIDIARIES  
 CONSOLIDATED FINANCIAL STATEMENTS

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**Soligenix, Inc. and Subsidiaries**  
**Consolidated Balance Sheets**

	September 30, 2016 (Unaudited )	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 5,655,200	\$ 4,921,545
Contracts and grants receivable	1,697,632	1,985,212
Prepaid expenses	225,614	244,267
Total current assets	7,578,446	7,151,024
Office furniture and equipment, net	33,050	47,366
Intangible assets, net	142,308	188,732
Total assets	\$ 7,753,804	\$ 7,387,122
<b>Liabilities and shareholders' equity (deficiency)</b>		
Current liabilities:		
Accounts payable	\$ 3,120,384	\$ 2,869,392
Accrued expenses	1,075,835	1,510,544
Notes payable	—	292,719
Warrant liability	1,324,909	2,434,101
Accrued compensation	62,245	298,675
Total current liabilities	5,583,373	7,405,431
Commitments and contingencies		
Shareholders' equity (deficiency):		
Preferred stock, 350,000 shares authorized; none issued or outstanding	—	—
Common stock, \$.001 par value; 10,000,000 shares and 5,000,000 shares authorized at September 30, 2016 and December 31, 2015, respectively; 3,754,224 shares and 3,126,952 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively <sup>(1)</sup>	3,755	3,127
Additional paid-in capital <sup>(1)</sup>	151,959,679	146,856,143
Accumulated deficit	(149,793,003 )	(146,877,579 )
Total shareholders' equity (deficiency)	2,170,431	(18,309 )
Total liabilities and shareholders' equity (deficiency)	\$ 7,753,804	\$ 7,387,122

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

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

**Soligenix, Inc. and Subsidiaries**  
**Consolidated Statements of Operations**  
**For the Three and Nine Months Ended September 30, 2016 and 2015**  
**(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues				
Contract revenue	\$ 2,959,254	\$ 3,874,199	\$ 8,750,291	\$ 5,668,746
Grant revenue	—	5,476	—	127,042
Total revenues	2,959,254	3,879,675	8,750,291	5,795,788
Cost of revenues	(2,630,046 )	(3,050,814 )	(7,204,920 )	(4,394,915 )
Gross profit	329,208	828,861	1,545,371	1,400,873
Operating expenses:				
Research and development	1,177,263	1,259,015	3,433,595	3,731,813
General and administrative	650,762	839,512	2,526,255	2,531,744
Total operating expenses	1,828,025	2,098,527	5,959,850	6,263,557
Loss from operations	(1,498,817 )	(1,269,666 )	(4,414,479 )	(4,862,684 )
Other income (expense):				
Change in fair value of warrant liability	(176,293 )	4,047,742	1,109,192	(907,368 )
Other income	—	—	390,599	—
Interest income (expense)	1,893	(3,728 )	(736 )	(2,616 )
Total other income (expense)	(174,400 )	4,044,014	1,499,055	(909,984 )
Net income (loss)	\$ (1,673,217 )	\$ 2,774,348	\$ (2,915,424 )	\$ (5,772,668 )
Basic net income (loss) per share <sup>(1)</sup>	\$ (0.49 )	\$ 1.05	\$ (0.90 )	\$ (2.26 )
Diluted net loss per share <sup>(1)</sup>	\$ (0.49 )	\$ (0.45 )	\$ (1.20 )	\$ (2.26 )
Basic weighted average common shares outstanding <sup>(1)</sup>	3,432,081	2,648,240	3,245,653	2,553,930
Diluted weighted average common shares outstanding <sup>(1)</sup>	3,432,081	2,829,058	3,347,837	2,553,930

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

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

**Soligenix, Inc. and Subsidiaries**  
**Consolidated Statement of Changes in Shareholders' Equity/(Deficiency)**  
**For the Nine Months Ended September 30, 2016**  
**(Unaudited)**

	Common Stock		Additional	Accumulated	
	Shares <sup>(1)</sup>	Par Value <sup>(1)</sup>	Paid-In	Deficit	Total
			Capital <sup>(1)</sup>		
<b>Balance, December 31, 2015</b>	<b>3,126,952</b>	<b>\$ 3,127</b>	<b>\$ 146,856,143</b>	<b>\$ (146,877,579)</b>	<b>\$ (18,309 )</b>
Issuance of common stock pursuant to Lincoln Park Equity Line	266,830	267	1,638,843	—	1,639,110
Costs associated with Lincoln Park Equity Line	—	—	(41,381 )	—	(41,381 )
Issuance of common stock to SciClone	352,942	353	2,999,647	—	3,000,000
Issuance of common stock to vendors	7,500	8	52,492	—	52,500
Share-based compensation expense	—	—	453,935	—	453,935
Net loss	—	—	—	(2,915,424 )	(2,915,424)
<b>Balance, September 30, 2016</b>	<b>3,754,224</b>	<b>\$ 3,755</b>	<b>\$ 151,959,679</b>	<b>\$ (149,793,003)</b>	<b>\$ 2,170,431</b>

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

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

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

	2016	2015
<b>Operating activities:</b>		
Net loss	\$ (2,915,424 )	\$ (5,772,668 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	67,902	184,496
Amortization of discount on debt	7,281	4,328
Share-based compensation	453,935	414,112
Gain on settlement liability	(390,599 )	—
Issuance of common stock for services	52,500	190,261
Change in fair value of warrant liability	(1,109,192 )	907,368
Change in operating assets and liabilities:		
Contracts and grants receivable	287,580	(1,069,976 )
Prepaid expenses	18,653	14,770
Accounts payable and accrued expenses	206,881	1,343,876
Accrued compensation	(236,430 )	(266,942 )
Total adjustments	(641,489 )	1,722,293
Net cash used in operating activities	(3,556,913 )	(4,050,375 )
<b>Investing activities:</b>		
Purchases of office furniture and equipment	(7,161 )	(22,098 )
Net cash used in investing activities	(7,161 )	(22,098 )
<b>Financing activities:</b>		
Proceeds from issuance of common stock pursuant to the equity line	1,639,110	1,615,025
Stock issuance costs associated with equity line purchase agreement	(41,381 )	(171,091 )
Repayment of notes payable	(300,000 )	—
Proceeds from issuance of common stock to SciClone	3,000,000	—
Proceeds from exercise of warrants	—	1,136,771
Net cash provided by financing activities	4,297,729	2,580,705
Net increase (decrease) in cash and cash equivalents	733,655	(1,491,768 )
Cash and cash equivalents at beginning of period	4,921,545	5,525,094
Cash and cash equivalents at end of period	\$ 5,655,200	\$ 4,033,326
<b>Supplemental disclosure of non cash financing activities:</b>		
Reclassification of warrant liability to additional paid in capital upon partial exercise of warrants issued in unit offering	\$ —	\$ 2,557,331
Notes payable issued in connection with Equity Purchase Agreement	\$ —	\$ —