SOLIGENIX, INC.
Form 424B3
May 13, 2016

Prospectus Supplement No. 1 **Filed Pursuant to Rule 424(b)(3)**

(To Prospectus dated April 29, 2016) **File No. 333-210665**

SOLIGENIX, INC.

5,600,000 SHARES OF COMMON STOCK

This Prospectus Supplement No. 1 (this "Prospectus Supplement") supplements the prospectus dated March 31, 2015 (the "Final Prospectus"), relating to the offer and sale of up to 5,600,000 shares of our common stock by Lincoln Park Capital Fund, LLC.

This Prospectus Supplement contains the Quarterly Report on Form 10-Q that we filed with the Securities and Exchange Commission on May 12, 2016. This Prospectus Supplement should be read in conjunction with, and may not be utilized without, the Final Prospectus, which is to be delivered with this Prospectus Supplement. This Prospectus Supplement is qualified by reference to the Final Prospectus except to the extent that the information in this Prospectus Supplement updates and supersedes the information contained in the Final Prospectus, including any supplements or amendments thereto.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Prospectus Supplement No. 1 dated May 13, 2016.

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended March 31, 2016

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. 000-16929

SOLIGENIX, INC.

(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation or organization)	**41-1505029** (I.R.S. Employer Identification Number)
29 EMMONS DRIVE, SUITE C-10 **PRINCETON, NJ** (Address of principal executive offices)	**08540** (Zip Code)

(609) 538-8200
(Registrant’s telephone number,

including area code)

Indicate by check whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web Site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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 definition of “accelerated filer” and “large accelerated filer” in Rule 112b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 6, 2016, 31,472,522 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

SOLIGENIX, INC.

Index

PART I - FINANCIAL INFORMATION

ITEM 1 - Financial Statements

Soligenix, Inc. and Subsidiaries

Consolidated Balance Sheets

	March 31, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$4,260,440	$4,921,545
Contracts and grants receivable	1,023,301	1,985,212
Prepaid expenses	89,525	244,267
Total current assets	5,373,266	7,151,024
Office furniture and equipment, net	44,440	47,366
Intangible assets, net	173,314	188,732
Total assets	$5,591,020	$7,387,122
Liabilities and shareholders' deficiency		
Current liabilities:		
Accounts payable	$4,632,771	$4,379,936
Notes payable	298,970	292,719
Warrant liability	1,673,944	2,434,101
Accrued compensation	35,669	298,675
Total current liabilities	6,641,354	7,405,431
Commitments and contingencies		
Shareholders' deficiency:		
Preferred stock, 350,000 shares authorized; none issued or outstanding	-	-
Common stock, $.001 par value; 50,000,000 shares authorized; 31,369,522 shares and 31,269,522 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	31,370	31,270
Additional paid-in capital	146,945,308	146,828,000
Accumulated deficit	(148,027,012)	(146,877,579)
Total shareholders' deficiency	(1,050,334)	(18,309)
Total liabilities and shareholders' deficiency	$5,591,020	$7,387,122

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

1

Soligenix, Inc. and Subsidiaries

Consolidated Statements of Operations

For the Three Months Ended March 31, 2016 and 2015

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
Contract revenue	$2,630,986	$712,406
Grant revenue	-	103,880
Total revenues	2,630,986	816,286
Cost of revenues	(2,232,335)	(527,399)
Gross profit	398,651	288,887
Operating expenses:		
Research and development	1,428,499	1,029,884
General and administrative	875,857	817,270
Total operating expenses	2,304,356	1,847,154
Loss from operations	(1,905,705)	(1,558,267)
Other income (expense):		
Change in fair value of warrant liability	760,157	(3,011,616)
Interest income (expense), net	(3,885)	561
Total other income (expense)	756,272	(3,011,055)
Net loss	$(1,149,433)	$(4,569,322)
Basic net loss per share	$(0.04)	$(0.19)
Diluted net loss per share	$(0.06)	$(0.19)
Basic weighted average common shares outstanding	31,279,412	24,405,813
Diluted weighted average common shares outstanding	32,600,727	24,405,813

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

2

Soligenix, Inc. and Subsidiaries

Consolidated Statement of Changes in Shareholders' Deficiency

For the Three Months Ended March 31, 2016

(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2015	31,269,522	$31,270	$146,828,000	$(146,877,579)	$(18,309)
Issuance of common stock pursuant to Lincoln Park Equity Line	100,000	100	(100)	-	-
Costs associated with Lincoln Park Equity Line	-	-	(19,003)	-	(19,003)
Share-based compensation expense	-	-	136,411	-	136,411
Net loss	-	-	-	(1,149,433)	(1,149,433)
Balance, March 31, 2016	31,369,522	$31,370	$146,945,308	$(148,027,012)	$(1,050,334)

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

Soligenix, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

For the Three Months Ended March 31,

(Unaudited)

	2016	2015
Operating activities:		
Net loss	$(1,149,433)	$(4,569,322)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	22,607	59,926
Common stock issued to vendors	-	101,360
Share-based compensation	136,411	142,025
Amortization of discount on debt	6,251	-
Change in fair value of warrant liability	(760,157)	3,011,616
Change in operating assets and liabilities:		
Contracts and grants receivable	961,911	449,347
Prepaid expenses	154,742	41,382
Accounts payable	252,835	(459,603)
Accrued compensation	(263,006)	(282,841)
Total adjustments	511,594	3,063,212
Net cash used in operating activities	(637,839)	(1,506,110)
Investing activities		
Purchases of office furniture and equipment	(4,263)	(11,553)
Net cash used in investing activities	(4,263)	(11,553)
Financing Activities:		
Net proceeds from issuance of common stock pursuant to the equity lines	-	246,525
Stock issuance cost associated with equity line purchase agreement	(19,003)	-
Proceeds from exercises of options and warrants	-	758,649
Net cash (used in) provided by financing activities	(19,003)	1,005,174
Net decrease in cash and cash equivalents	(661,105)	(512,489)
Cash and cash equivalents at beginning of period	4,921,545	5,525,094
Cash and cash equivalents at end of period	$4,260,440	$5,012,605
Supplemental disclosure of non cash investing and financing activities:		
Reclassification of warrant liability to additional paid in capital upon partial exercises of warrants issued in unit offering	$-	$1,648,811

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

4

Soligenix, Inc.

Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

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

The Company's BioTherapeutics business segment is developing a first-in-class photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"), proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201), and its novel innate defense regulator ("IDR") technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer.

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

The Company generates revenues under government grants primarily from the National Institutes of Health (the "NIH") and government contracts from BARDA and NIAID.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology,

compliance with the United States Food and Drug Administration (the U.S. “FDA”) regulations, litigation, and product liability. Results for the three months ended March 31, 2016 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of March 31, 2016, the Company had cash and cash equivalents of $4,260,440 as compared to $4,921,545 as of December 31, 2015, representing a decrease of $661,105 or 13%. The decrease in cash was primarily due to net cash used in operations of $637,839. As of March 31, 2016, the Company had working capital of $405,856 which excludes a non-cash warrant liability of $1,673,944, as compared to working capital of $2,179,694 as of December 31, 2015, which excludes a non-cash warrant liability of $2,434,101, representing a decrease of $1,773,838 or 81% in working capital. This decrease is primarily related to expenditures to support the Phase 2 clinical trial of SGX942 and the pivotal Phase 3 clinical trial of SGX301 for the treatment of CTCL.

Based on the Company’s current rate of cash outflows, cash on hand, proceeds from its government contract and grant programs, availability of funds from equity lines 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.

Management's business strategy can be outlined as follows:

Complete enrollment and report preliminary results in the pivotal Phase 3 clinical trial with SGX301 for the treatment of CTCL;
Initiate a pivotal Phase 3 clinical trial of oral BDP, known as SGX203, for the treatment of pediatric Crohn's disease;
Continue to collect the long-term follow-up safety data from the SGX942 Phase 2 proof-of-concept study in the treatment of oral mucositis in head and neck cancer patients and publish the findings from this study;
Obtain FDA agreement on a pivotal Phase 2b/3 protocol of SGX942 in the treatment of oral mucositis in head and neck cancer patients;
Continue development of RiVax™ in combination with ThermoVax® technology, to develop new heat stable vaccines in biodefense;
Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS;
Continue to apply for and secure additional government funding for each of the other BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
Pursue business development opportunities for the Company's pipeline programs, as well as explore merger/acquisition strategies; and
Acquire or in-license new clinical-stage compounds for development.

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

The Company has up to $40.3 million in active government funding still available to support its associated research programs through 2016 and beyond. The Company plans to submit additional contract and grant applications for further support of its programs with various funding agencies.
The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.
The Company will pursue Net Operating Loss ("NOL") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $488,933 in proceeds of the sale of NJ NOL in 2015, the Company expects to participate in the program during 2016 and beyond.
The Company plans to pursue potential partnerships for pipeline programs. However, there can be no assurances that we can consummate such a transaction.
The Company has $8.2 million available from equity facilities expiring in November 2016 and $12.0 million from equity facilities expiring in March 2019; and
The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is currently evaluating additional equity financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Operating Segments

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

Cash and cash equivalents

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

Contracts and Grants Receivable

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

Intangible Assets

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

Company's rights, and perhaps extend the lives of the patents. The Company capitalizes such costs and amortizes intangibles on a straight-line basis over their expected useful life – generally a period of 11 to 16 years.

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

The Company did not capitalize any patent related costs during the three months ended March 31, 2016 and 2015.

Impairment of Long-Lived Assets

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

The Company did not record any impairment of long-lived assets for the three months ended March 31, 2016 and 2015.

Fair Value of Financial Instruments

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

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

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

Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.
Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.
Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

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

8

Revenue Recognition

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

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, *Research and Development*. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Accounting for Warrants

The Company considered FASB ASC 815, *Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock*, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock, and, therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. The Company evaluated the provisions and determined that warrants issued in connection with the Company's June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of the Company's common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants 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 the Company's stock and therefore are accounted for as equity instruments for 2016 and 2015.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon

issuance). Stock options issued to employees 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, the Company issues restricted shares of common stock to vendors and consultants as compensation for services performed. Typically these instruments vest upon issuance and therefore the entire share-based compensation expense is recognized upon issuance to the vendors and/or consultants.

Share-based compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 718, *Stock Compensation*, and FASB ASC 505-50, *Equity-Based Payments to Non-Employees*, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The fair value is remeasured each reporting period until performance is complete.

For the three months ended March 31, 2016 and 2015, the Company issued stock options at a weighted average exercise price of $0.89 and $1.10 per share, respectively. The fair value of options issued during the three months ended March 31, 2016 and 2015 were estimated using the Black-Scholes option-pricing model and the following assumptions:

a dividend yield of 0%;
an expected life of 4 years;
volatility of 121% for 2016 and ranging from 139% - 141% for 2015
forfeitures at a rate of 12%; and
risk free interest rates ranging from 1.19% - 1.52% and .99 - 1.33% for 2016 and 2015 respectively.

The fair value of each option grant made during 2016 and 2015 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option vesting periods, which approximates the service period.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax 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 the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through March 31, 2016 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2016 and 2015. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at March 31, 2016 and December 31, 2015.

Earnings Per Share

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

a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

	For the Quarter Ended March 31, 2016	**For the Quarter Ended** March 31, 2015
Numerator:		
Net loss for basic earnings per share	$(1,149,433)	$(4,569,322)
Less change in fair value of warrant liability	760,157	-
Net loss for diluted earnings per share	$(1,909,590)	$(4,569,322)
Denominator:		
Weighted-average basic common shares outstanding	31,279,412	24,405,813
Assumed conversion of dilutive securities:		
Common stock purchase warrants	1,321,315	-
Denominator for diluted earnings per share – adjusted weighted-average shares	32,600,727	24,405,813
Basic net loss per share	$(0.04)	$(0.19)
Diluted net loss per share	$(0.06)	$(0.19)

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

	For the Quarter Ended March 31, 2016	For the Quarter Ended March 31, 2015
Common stock purchase warrants	1,889,191	6,085,714
Stock options	2,824,737	2,272,022
Total	4,713,928	8,357,736

The weighted average exercise price of the Company’s stock options and warrants outstanding at March 31, 2016 were $2.10 and $0.74 per share, respectively, and at March 31, 2015 were $2.34 and $1.25 per share, respectively.

Use of Estimates and Assumptions

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

Recently Issued Accounting Pronouncements

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

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

Note 3. Intangible Assets

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

	Weighted Average Remaining Amortization Period (years)	Cost	Accumulated Amortization	Net Book Value
March 31, 2016				
Licenses	3.5	$462,234	$ 340,524	$121,710
Patents	0.8	1,893,185	1,841,581	51,604
Total		$2,355,419	$ 2,182,105	$173,314
December 31, 2015				
Licenses	3.8	$462,234	$ 333,732	$128,502
Patents	1.1	1,893,185	1,832,955	60,230
Total		$2,355,419	$ 2,166,687	$188,732

Amortization expense was $15,418 and $54,039 for the three months ended March 31, 2016 and 2015, respectively.

Based on the balance of licenses and patents at March 31, 2016, the annual amortization expense for each of the succeeding four years is estimated to be as follows:

	Amortization Expense
April 1 through December 31,2016	$ 46,382
2017	$ 61,800
2018	$ 37,300
2019	$ 27,832

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

Note 4. Notes Payable

On July 29, 2015, the Company entered into equity purchase agreements (the “Equity Line Purchase Agreements”) and registration rights agreements with certain accredited institutional investors. Under the Equity Line Purchase Agreements, the investors have agreed to purchase from the Company up to an aggregate of $10 million worth of shares of common stock, from time to time.

In consideration for entering into the Equity Line Purchase Agreements, the Company issued to the investors promissory notes having an aggregate principal amount of $300,000, which were recorded as stock issuance costs. The promissory notes were paid on April 15, 2016, and had an issuance date present value of $282,071. The promissory notes did not include terms for interest, therefore the interest was imputed at 9%. Total discount amortization of $6,251 was recorded as interest expense for the three months ended March 31, 2016. The discount is being accreted over the term of the promissory notes using the effective interest rate method.

Note 5. Warrant Liability

Warrants issued in connection with the Company's June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of its common stock (or "down-round" provision) and contain net settlement provisions. As a result, the Company accounts for these warrants as liabilities instead of equity instruments. Down-round provisions reduce the exercise or conversion price of a warrant if the Company issues equity shares for a price that is lower than the exercise or conversion price of the warrants. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of exercising the warrant by paying cash. The Company evaluates whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a "fixed for fixed" option. As a result of the Company's December 2014 registered public unit offering, the exercise price of warrants outstanding in connection with the public offering completed in June 2013 was adjusted to $0.61 per share. As a result of the Company's December 2015 drawdown on the Equity Line Purchase Agreement, the exercise price of warrants outstanding in connection with the public offering completed in June 2013 was adjusted to $0.51 per share.

The Company recognized these warrants as liabilities at their fair value on the date of grant and remeasures them to fair value on each reporting date.

The Company recognized an initial warrant liability for the warrants issued in connection with the registered public offering completed in June 2013 totaling $4,827,788, which was based on the June 25, 2013 closing price of a share of the Company's common stock as reported on OTC Markets of $0.96. On March 31, 2016, the closing price of the Company's common stock as reported on OTC Markets was $0.84. Due to the fluctuations in the market value of the Company's common stock from December 31, 2015 through March 31, 2016, the Company recognized non-cash income of $760,157 for the change in the fair value of the warrant liability for the three months ended March 31, 2016.

The assumptions used in connection with the valuation of warrants issued using the binomial method were as follows:

	December 31, 2015	March 31, 2016
Number of shares underlying the warrants	3,036,928	3,036,928
Exercise price	$ 0.51	$0.51
Volatility	98 %	98 %
Risk-free interest rate	1.19 %	0.80 %

Expected dividend yield	0	0
Expected warrant life (years)	2.48	2.24
Stock Price	$ 1.13	$0.84

The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3). The table reflects gains for the three months ended March 31, 2016 for the financial liability categorized as Level 3 as of March 31, 2016**.**

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

	December 31, 2015	Decrease from Warrants Exercised in 2016	Decrease in Fair Value	March 31, 2016
Warrant liability	$ 2,434,101	-	$760,157	$1,673,944

Note 6. Income Taxes

The Company had gross NOLs at December 31, 2015 of approximately $90,891,000 for federal tax purposes and approximately $5,273,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which will begin to expire in 2018. In addition, the Company has $4,909,000 of various tax credits which expire from 2018 to 2034. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carry forwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is likely that the utilization of the NOLs may be substantially limited.

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

The Company has no tax provision for the three month periods ended March 31, 2016 and 2015 due to losses incurred and the recognition of full valuation allowances recorded against net deferred tax assets.

Note 7. Shareholders' Deficiency

Preferred Stock

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

Common Stock

During the three months ended March 31, 2016, the Company issued the following shares of common stock:

the Company issued Lincoln Park Capital 100,000 shares of common stock as consideration for entering into an equity line purchase agreement.

Equity Line Purchase Agreements

In March 2016, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). The Lincoln Park equity facility allows the Company to require Lincoln Park to purchase up to 100,000 shares ("Regular Purchase") of the Company's common stock every two business days, up to an aggregate of $12.0 million over approximately a 36-month period with such amounts increasing as the quoted stock price increases. The Regular Purchase may be increased up to 150,000 shares of common stock if the closing price of the common shares is not below $1.00, up to 200,000 shares of common stock if the closing price of the common shares is not below $1.50 and up to 250,000 shares of common stock if the closing price of the common shares is not below $2.00. The purchase price for the Regular Purchase shall be equal to the lesser of (i) the lowest sale price of the common shares during the purchase date, or (ii) the average of the three lowest closing sale prices of the common shares during the twelve business days prior to the purchase date. Each Regular Purchase shall not exceed $750,000. Furthermore, for each purchase by Lincoln Park, additional commitment shares in commensurate amounts up to a total of 500,000 shares will be issued based upon the relative proportion of the aggregate amount of $12.0 million. In addition to the Regular Purchase and provided that the closing price of the common shares is not below $0.75 on the purchase date, the Company in its sole discretion may direct Lincoln Park on each purchase date to purchase on the next stock trading day (Accelerated Purchase Date") additional shares of Company stock up to the lesser of (i) three times the number of shares purchased following a Regular Purchase or (ii) 30% of the trading volume of shares traded on the Accelerated Purchase Date at a price equal to the lesser of the closing sale price on the Accelerated Purchase Date or 95% of the Accelerated Purchase Date's volume weighted average price.

As part of the agreement, the Company issued 100,000 shares of common stock as consideration for its commitment to purchase shares of our common stock under the purchase agreement. The value of these shares on the date granted was $81,000.

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

From the date that the SEC declared the registration statement effective, in August 2015, until December 31, 2016, the Company had the right to sell up to $5 million, $4 million and $1 million worth of shares of common stock to Kodiak Capital, Kingsbrook and River North, respectively.

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

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

In December 2015, a second drawdown was made, whereby under the Equity Line Purchase Agreements, the Company issued 3,936,235 shares of common stock receiving proceeds of $2,000,000.

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

Note 8. Commitments and Contingencies

The Company has commitments of approximately $450,000 as of March 31, 2016 for several licensing agreements with consultants and universities. Additionally, the Company has collaboration and license agreements, which upon clinical or commercialization success, may require the payment of milestones of up to $7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur. As of March 31, 2016, no milestone or royalty payments have been paid or accrued.

In December 2014, the Company entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months is approximately $12,300 per month, or approximately $20.85 per square foot. This rent increases to approximately $12,375 per month, or approximately $20.95 per square foot, for the next 12 months and approximately $12,460 per month, or approximately $21.13 per square foot for the remainder of the lease.

On September 3, 2014, the Company entered into an asset purchase agreement with Hy Biopharma, Inc. (“Hy Biopharma”) pursuant to which the Company acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma’s synthetic hypericin product. As consideration for the assets acquired, the Company paid $250,000 in cash and issued 1,849,113 shares of common stock with a fair value based on the Company’s stock price on the date of grant of $3,750,000. These amounts were charged to research and development expense during the third quarter of 2014 as the assets will be used in the Company’s research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the United States. Provided all future success-oriented milestones are attained, the Company will be required to make additional payments of up to $10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company not to exceed 19.9% ownership of Company’s outstanding stock. As of March 31, 2016, no milestone payments have been paid or accrued.

In February 2007, the Company’s Board of Directors authorized the issuance of 50,000 shares of the Company’s common stock to Dr. Schaber immediately prior to the completion of a transaction, or series or a combination of related transactions, negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party. Dr. Schaber’s amended employment agreement includes the Company’s obligation to issue such shares if such event occurs.

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

Year	Research and Development	**Property and Other Leases**	**Total**
April 1 through December 31, 2016	$ 50,000	$ 118,000	$168,000
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	$ 450,000	$ 321,000	$771,000

16

Note 8. Operating Segments

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

	Three Months Ended	
	March 31,	
	2016	2015
Contract/Grant Revenue		
Vaccines/BioDefense	$2,630,986	$802,314
BioTherapeutics	-	13,972
Total	$2,630,986	$816,286
Income/(Loss) from Operations		
Vaccines/BioDefense	$317,991	$84,681
BioTherapeutics	(1,245,585)	(764,876)
Corporate	(978,111)	(878,072)
Total	$(1,905,705)	$(1,558,267)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$10,019	$9,786
BioTherapeutics	10,433	48,374
Corporate	2,155	1,766
Total	$22,607	$59,926
Interest Income/(Expense)		
Corporate	$(3,885)	$561
Share-Based Compensation		
Vaccines/BioDefense	$28,006	$24,592
BioTherapeutics	34,832	29,256
Corporate	73,573	88,177
Total	$136,411	$142,025

As of	As of
March 31,	December 31, 2015

	2016	
Identifiable Assets		
Vaccines/BioDefense	$1,150,768	$2,123,676
BioTherapeutics	70,274	76,183
Corporate	4,369,978	5,187,263
Total	$5,591,020	$7,387,122

17

ITEM 2 – Management's Discussion and Analysis OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes, Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2015. This report contains forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expressions, however, these words are not the exclusive means of identifying such statements. In addition, any statements that refer to expectations projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the U.S. Securities and Exchange Commission or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the U.S. Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business. We provide addresses to internet sites solely for the information to investors. We do not intend any addresses to be active links or to otherwise incorporate the contents of any website into this report.

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 first-in-class photodynamic therapy (SGX301) utilizing topical synthetic hypericin activated with safe visible light for the treatment of cutaneous T-cell lymphoma ("CTCL"), proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201), and our novel innate defense regulator ("IDR") technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome ("GI ARS") therapeutic candidate and SGX943, our

melioidosis therapeutic candidate. The development of our vaccine program 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 government contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and NIAID to advance the development of OrbeShield® for the treatment of GI ARS.

An outline for our business strategy follows:

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

Initiate a pivotal Phase 3 clinical trial of SGX203 for the treatment of pediatric Crohn's disease;
Continue to collect the long-term follow-up safety data from the SGX942 Phase 2 proof-of-concept study in 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;
Continue development of RiVax™ in combination with our ThermoVax® technology to develop new heat stable vaccines in biodefense;
Advance the preclinical and manufacturing development of OrbeShield® as a biodefense medical countermeasure for the treatment of GI ARS;
Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
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.

Corporate Information

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

Our Products in Development

The following tables summarize our products 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 2016
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; seek to obtain FDA agreement on the Phase 2b/3 protocol in the second half of 2016
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed in June 2013, efficacy data, pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed; Phase 3 clinical trial planned for the second half of 2016, with data expected in the first half of 2018
SGX201**	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated; Phase 2 trial planned for the first half of 2017

Vaccine Thermostability Platform**

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

BioDefense Products**

Soligenix Product	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 2016
OrbeShield®	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943	Melioidosis	Pre-clinical

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

BioTherapeutics Overview

SGX301 – for Treating Cutaneous T-Cell Lymphoma

SGX301 is a novel, first-in-class, photodynamic therapy that utilizes safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a photosensitizer which is topically applied to skin lesions and then activated by fluorescent light 16 to 24 hours later. Hypericin is also found in several species of *Hypericum* plants, although the drug used in SGX301 is chemically synthesized by a proprietary manufacturing process and not extracted from plants. Importantly, hypericin is optimally activated with visible light thereby avoiding the negative consequences of ultraviolet light. Other light therapies using UVA light result in serious adverse effects including secondary skin cancers.

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

Hypericin is one of the most efficient known generators of singlet oxygen, the key component for phototherapy. The generation of singlet oxygen induces necrosis and apoptosis in adjacent cells. The use of topical hypericin coupled with directed visible light results in generation of singlet oxygen only at the treated site. We believe that the use of visible light (as opposed to cancer-causing ultraviolet light) is a major advance in photodynamic therapy. In a published Phase 2 clinical study in CTCL, after six weeks of twice weekly therapy, a majority of patients experienced a statistically significant 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 in the treatment of CTCL during December 2015 and anticipate data in the second half of 2016.

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

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 be safe and well-tolerated in all dose groups when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. 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* bacterial infections, acinetobacter, melioidosis, and acute radiation syndrome, with potential opportunities for non-dilutive funding to support the development.

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 in 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. In addition to identifying the optimal dose of 1.5 mg/kg, this study achieved all objectives, including a trend towards 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 significant 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 is expected to be submitted for future presentation and publication.

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.

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 B*DP*

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

release BDP in the lower sections of the GI tract.

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

We are pursuing orphan drug designations for relevant indications as appropriate in both the U.S. and Europe. An orphan drug designation provides for seven 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 two tablet delivery system of BDP specifically designed for oral use that allows for administration of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has given SGX203 orphan drug designation as well as Fast Track designation for the treatment of pediatric Crohn's disease.

We anticipate initiating a Phase 3 clinical study of SGX203 in the treatment of pediatric Crohn's disease in the second half of 2016.

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.

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.

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 B 12 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.

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).

26

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 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 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 Soligenix and to UTSW where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. To date, we and UTSW have collectively received approximately $25 million in grant funding from the NIH for the development of RiVax™. 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.

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 Investigations 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). 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, a U.S. Senator and a judge tested positive for ricin.

The Centers for Disease Control 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 Soligenix's 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.

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 meliodosis. 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 recrudesce. 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.

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 the 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 for our current product candidates in both the domestic and international markets. We believe that patent rights are one of our most valuable assets. Patents and patent applications are key components of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industry partners. These rights can also be sold or sub-licensed as part of our strategy to partner our product candidates at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents designed to protect, preserve and maintain our rights, and perhaps to 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 March 31, 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, contract and grants receivable, accounts 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 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 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 in our outstanding warrants and determined that warrants issued in connection with our June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of our common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants are recognized as liabilities at their fair value on the date of grant and remeasured at fair value on each reporting date. All other warrants issued were indexed to our own stock and, therefore, are accounted for as equity instruments for 2016 and 2015.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees 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 f