

SOLIGENIX, INC.
Form 10-Q
May 14, 2015

**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, 2015

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 8, 2015, 25,714,275 shares of the registrant's common stock (par value, \$.001 per share) were outstanding.

SOLIGENIX, INC.

Index

Description	<u>Page</u>
Part I FINANCIAL INFORMATION	
Item 1 Consolidated Financial Statements	3
Consolidated Balance Sheets as of March 31, 2015 (unaudited) and December 31, 2014	3
Consolidated Statements of Operations for the Three Months Ended March 31, 2015 and 2014 (unaudited)	4
Consolidated Statement of Changes in Shareholders' Deficiency for the Three Months Ended March 31, 2015 (unaudited)	5
Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2015 and 2014 (unaudited)	6
Notes to Consolidated Financial Statements	7
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3 Quantitative and Qualitative Disclosures About Market Risk	37
Item 4 Controls and Procedures	37
Part II OTHER INFORMATION	
Item 1A Risk Factors	38
Item 2 Unregistered Sales of Equity Securities and Use of Proceeds	38
Item 6 Exhibits	40
SIGNATURES	39

PART I - FINANCIAL INFORMATION**ITEM 1 - Financial Statements****Soligenix, Inc. and Subsidiaries****Consolidated Balance Sheets**

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$5,012,605	\$5,525,094
Contracts and grants receivable	345,420	794,767
Prepaid expenses	131,546	172,928
Total current assets	5,489,571	6,492,789
Office furniture and equipment, net	57,176	51,510
Intangible assets, net	355,910	409,949
Total assets	\$5,902,657	\$6,954,248
Liabilities and shareholders' deficiency		
Current liabilities:		
Accounts payable	\$2,543,942	\$3,003,545
Warrant liability	5,152,367	3,789,562
Accrued compensation	32,189	315,030
Total current liabilities	7,728,498	7,108,137
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; 25,339,364 shares and 23,936,568 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	25,340	23,937
Additional paid-in capital	141,764,490	138,868,523
Accumulated deficit	(143,615,671)	(139,046,349)
Total shareholders' deficiency	(1,825,841)	(153,889)
Total liabilities and shareholders' deficiency	\$5,902,657	\$6,954,248

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

Soligenix, Inc. and Subsidiaries**Consolidated Statements of Operations****For the Three Months Ended March 31, 2015 and 2014****(Unaudited)**

	Three Months Ended	
	March 31,	
	2015	2014
Revenues:		
Grant revenue	\$ 103,880	\$ 244,290
Contract revenue	712,406	666,307
Total revenues	816,286	910,597
Cost of revenues	(527,399)	(628,981)
Gross profit	288,887	281,616
Operating expenses:		
Research and development	1,029,884	1,030,621
General and administrative	817,270	840,904
Total operating expenses	1,847,154	1,871,525
Loss from operations	(1,558,267)	(1,589,909)
Other income (expense):		
Change in fair value of warrant liability	(3,011,616)	(1,742,090)
Interest income	561	291
Total other income (expense)	(3,011,055)	(1,741,799)
Net loss	\$(4,569,322)	\$(3,331,708)
Basic and diluted net loss per share	\$(0.19)	\$(0.17)
Basic and diluted weighted average common shares outstanding	24,405,813	19,739,470

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

Soligenix, Inc. and Subsidiaries**Consolidated Statement of Changes in Shareholders' Deficiency****For the Three Months Ended March 31, 2015****(Unaudited)**

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2014	23,936,568	\$23,937	\$138,868,523	\$(139,046,349)	\$(153,889)
Issuance of common stock pursuant to Lincoln Park Equity Line	153,010	153	246,372	-	246,525
Issuance of common stock to vendors	66,000	66	101,294	-	101,360
Reclassification of warrant liability upon partial exercises of warrants issued in unit offering	-	-	1,648,811	-	1,648,811
Issuance of common stock from exercises of warrants	1,183,786	1,184	757,465	-	758,649
Share-based compensation expense	-	-	142,025	-	142,025
Net loss	-	-	-	(4,569,322)	(4,569,322)
Balance, March 31, 2015	25,339,364	\$25,340	\$141,764,490	\$(143,615,671)	\$(1,825,841)

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)**

	2015	2014
Operating activities:		
Net loss	\$(4,569,322)	\$(3,331,708)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	59,926	62,087
Common stock issued to vendors	101,360	153,540
Warrants issued to vendors	-	4,775
Share-based compensation	142,025	176,662
Change in fair value of warrant liability	3,011,616	1,742,090
Change in operating assets and liabilities:		
Grants receivable	449,347	172,740
Taxes receivable	-	750,356
Prepaid expenses	41,382	37,771
Accounts payable	(459,603)	32,338
Accrued compensation	(282,841)	(188,430)
Total adjustments	3,063,212	2,943,929
Net cash used in operating activities	(1,506,110)	(387,779)
Investing activities		
Purchases of fixed assets	(11,553)	(19,863)
Net cash used in investing activities	(11,553)	(19,863)
Financing Activities:		
Net proceeds from issuance of common stock pursuant to the equity line	246,525	158,250
Proceeds from exercises of warrants	758,649	-
Net cash provided by financing activities	1,005,174	158,250
Net decrease in cash and cash equivalents	(512,489)	(249,392)
Cash and cash equivalents at beginning of period	5,525,094	5,856,242
Cash and cash equivalents at end of period	\$5,012,605	\$5,606,850
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	\$502,025

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

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 developing product candidates intended to address unmet medical needs in the areas of inflammation, oncology, and biodefense. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense.

The Company’s BioTherapeutics business segment is developing a first-in-class photo-dynamic therapy (SGX301) utilizing 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 (SGX942) for the treatment of oral mucositis.

The Company’s Vaccines/BioDefense business segment includes active development programs for RiVax™, its ricin toxin vaccine candidate, VeloThrax™, an anthrax vaccine candidate, and OrbeShield™, a GI acute radiation syndrome (“GI ARS”) therapeutic candidate and SGX943, a melioidosis therapeutic candidate. The development of the vaccine programs is supported by the Company’s heat stabilization technology, known as ThermoVax™, under existing and on-going government contract funding. With the recently awarded government contracts 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. Additionally, the Company entered into a global and exclusive channel collaboration with Intrexon Corporation (“Intrexon”) through which it intends to develop and commercialize a human monoclonal antibody therapy (SGX101) to treat melioidosis.

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, 2015 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of March 31, 2015, the Company had cash and cash equivalents of \$5,012,605 as compared to \$5,525,094 as of December 31, 2014, representing a decrease of \$512,489 or 9%. As of March 31, 2015, the Company had working capital of \$2,913,440 as compared to working capital of \$3,174,214 as of December 31, 2014, which excludes a non-cash warrant liability of \$5,152,367 and \$3,789,562, respectively, representing a decrease of \$260,774 or 8%. This decrease is primarily related to expenditures to support the Phase 2 clinical trial with SGX942 for the treatment of oral mucositis in head and neck cancer.

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 the Lincoln Park Capital Fund, LLC ("Lincoln Park") equity line 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:

Conduct a Phase 3 clinical trial of SGX301 for the treatment of CTCL;
Conduct a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
Initiate a Phase 3 clinical trial of oral BDP, known as SGX203, for the treatment of pediatric Crohn's disease;
Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis;
Develop RiVax™ and VeloThrax™ in combination with the Company's ThermoVax™ technology, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
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 Company's BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
Acquire or in-license new clinical-stage compounds for development; and
Explore other business development and merger/acquisition strategies an example of which is the collaboration with Intrexon.

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

The Company has up to \$50.5 million in active government contract and grant funding still available to support its associated research programs through 2015 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, in December 2014, of \$616,872 in proceeds pursuant to NOL sales in 2014, the Company expects to participate in the program during 2015 and beyond.

The Company has a \$10.6 million equity facility, with Lincoln Park through October 2016, of which approximately \$9.3 million is available.

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 original maturities of three months or less 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 and perhaps extending the lives of the patents. The Company capitalizes such costs and amortizes intangibles on a straight-line basis over their expected useful life –

generally a period of 11 to 16 years.

The Company did not capitalize any patent related costs during the three months ended March 31, 2015 and 2014.

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, 2015 and 2014.

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, 2015. 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, accounts receivable, accounts payable and accrued expenses 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 June 2013 offering were accounted for as derivatives. See Note 4, *Warrant Liability*.

Revenue Recognition

The Company's revenues are primarily generated from government contracts and grants. Revenue is recognized in accordance with FASB ASC 605, *Revenue Recognition*, and/or ASC 605-25 *Revenue Recognition – Multiple Element Arrangements*. 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, stock 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. The Company evaluated the warrants' 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 2015 and 2014.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of grant. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees vest 25% on the grant date, then 25% each subsequent year for a period of three years. Stock options vest over each three-month period from the date of issuance to the end of the three year period. These options have a ten year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position, the options will expire within three months, unless otherwise extended by the Board.

From time to time, 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 of options issued during the three months ended March 31, 2015 and 2014 was estimated using the Black-Scholes option-pricing model and the following assumptions:

a dividend yield of 0%;
an expected life of 4 years;
volatilities ranging from of 139% - 141% and 133% - 135% for 2015 and 2014, respectively
forfeitures at a rate of 12%; and
risk free interest rates ranging from of 0.99% - 1.31% and 1.11% - 1.33% for 2015 and 2014 respectively.

The weighted average fair value of each option grant made during 2015 and 2014 was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option vesting periods, which approximates the service period.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including 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, 2015 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 2015 and 2014. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at March 31, 2015 and December 31, 2014. Tax years beginning in 2011 for federal purposes are generally subject to examination by taxing authorities, although net operating losses from those years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

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, 2015	For the Quarter Ended March 31, 2014
Basic and diluted numerator:		
Net loss	\$(4,569,322)	\$(3,331,708)

Basic and diluted Denominator:

Weighted-average outstanding **24,405,813** 19,739,470

Basic and diluted net loss per share **\$(0.19**) \$(0.17)

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, 2015	For the Quarter Ended March 31, 2014
Common stock purchase warrants	6,085,714	6,808,324
Stock options	2,272,022	2,127,699
Total	8,357,736	8,936,023

The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2015 were \$2.34 and \$1.25 per share, respectively, and at March 31, 2014 were \$2.57 and \$2.08 per share, respectively.

Use of Estimates and Assumptions

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

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
<u>March 31, 2015</u>				
Licenses	4.5	\$462,234	\$313,211	\$149,023
Patents	1.7	1,893,185	1,686,298	206,887
Total	2.4	\$2,355,419	\$1,999,509	\$355,910
<u>December 31, 2014</u>				
Licenses	4.7	\$462,234	\$306,495	\$155,739
Patents	1.9	1,893,185	1,638,975	254,210
Total	2.6	\$2,355,419	<u>\$1,945,470</u>	\$409,949

Amortization expense was \$54,039 and \$54,712 for the three months ended March 31, 2015 and 2014, respectively.

Based on the balance of licenses and patents at March 31, 2015, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
April 1 through December 31,2015	\$ 162,100
2016	\$ 81,900
2017	\$ 37,300
2018	\$ 37,300
2019	\$ 37,300

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

Note 4. 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.

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. During the three months ended March 31, 2015, 1,148,786 warrants were exercised. The fair value of the warrants exercised, or \$1,648,811, was reclassified from warrant liability to additional paid-in capital. On March 31, 2015, the closing price of the Company's common stock as reported on OTC Markets was \$1.69. Due to the fluctuations in the market value of the Company's common stock from December 31, 2014 through March 31, 2015, the Company recognized a non-cash charge of \$3,011,616 for the change in the fair value of the warrant liability for the three months ended March 31, 2015.

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

	December 31, 2014	Exercised during 2015	March 31, 2015	
Number of shares underlying the warrants	4,723,357	1,141,786	3,581,571	
Exercise price	\$ 0.61	\$0.61	\$0.61	
Volatility	128	% 119	% 119	%

Edgar Filing: SOLIGENIX, INC. - Form 10-Q

Risk-free interest rate	1.38	%	0.89	%	0.89	%
Expected dividend yield	0		0		0	
Expected warrant life (years)	3.5		3.33		3.24	
Stock Price	\$ 0.98		\$ 1.69		\$ 1.69	

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 losses for the period ended March 31, 2015 for the financial liability categorized as Level 3 as of March 31, 2015.

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

	December 31, 2014	Decrease from Warrants Exercised in 2015	Increase in Fair Value	March 31, 2015
Warrant liability	\$ 3,789,562	\$(1,648,811)	\$3,011,616	\$5,152,367

Note 5. Income Taxes

The Company had NOLs at December 31, 2014 of approximately \$86,120,000 for federal tax purposes and approximately \$5,263,000 of New Jersey NOL carry forwards remaining after the sale of unused net operating loss carry forwards, portions of which are currently expiring each year through 2034. In addition, the Company has \$3,556,000 of various tax credits that 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. The Company is no longer subject to Federal income tax assessment for years before 2011 for Federal and 2010 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination and adjustments by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

The Company has no tax provision for the three month periods ended March 31, 2015 and 2014 due to losses incurred and the recognition of full valuation allowances recorded against net deferred tax assets.

Note 6. Shareholders’ Equity

Preferred Stock

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

Common Stock

During the three months ended March 31, 2015, the Company issued the following shares of common stock:

In seventeen separate transactions, the Company issued 1,183,786 shares of common stock in connection with warrant exercises;

In two separate transactions, the Company issued 153,010 shares of common stock pursuant to the Lincoln Park facility; and

In three separate transactions, the Company issued 66,000 shares of common stock as partial consideration for services performed.

Note 7. Commitments and Contingencies

The Company has commitments of approximately \$500,000 as of March 31, 2015 for 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.

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.

On April 27, 2013, the Company entered into an exclusive channel collaboration agreement (the “Channel Agreement”) with Intrexon to use Intrexon’s advanced human antibody discovery, isolation and production technologies for the development of human monoclonal antibody therapies for a new biodefense application targeting melioidosis. The Channel Agreement grants an exclusive worldwide license to use specified patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale and offer for sale of products for the treatment of melioidosis through the use of exogenously produced human recombinant monoclonal antibodies. The Channel Agreement, upon clinical or commercialization success, may require the payment of certain milestones payments up to \$7 million, if and when achieved.

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, 2015	\$ 100,000	\$ 99,000	\$199,000
2016	100,000	157,000	257,000
2017	100,000	152,000	252,000
2018	100,000	52,000	152,000
2019	100,000	-	100,000
Total	\$ 500,000	\$ 460,000	\$960,000

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,	
	2015	2014
Contract/Grant Revenue		
Vaccines/BioDefense	\$802,314	\$877,045
BioTherapeutics	13,972	33,552
Total	\$816,286	\$910,597
Income/(Loss) from Operations		
Vaccines/BioDefense	\$84,681	\$139,404
BioTherapeutics	(764,876)	(1,035,591)
Corporate	(878,072)	(693,722)
Total	\$(1,558,267)	\$(1,589,909)
Amortization and Depreciation Expense		
Vaccines/BioDefense	\$9,786	\$9,935
BioTherapeutics	48,374	49,939
Corporate	1,766	2,213
Total	\$59,926	\$62,087
Interest Income		
Corporate	\$561	\$291
Share-Based Compensation		
Vaccines/BioDefense	\$24,592	\$10,450
BioTherapeutics	29,256	76,121
Corporate	88,177	90,091
Total	\$142,025	\$176,662

As of	
March 31,	As of
2015	December 31,
	2014

Identifiable Assets

Vaccines/BioDefense	\$568,565	\$ 1,025,220
BioTherapeutics	161,355	204,308
Corporate	5,172,737	5,724,720
Total	\$5,902,657	\$ 6,954,248

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, 2014. 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 the 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.

Our Business Overview

We are a late-stage biopharmaceutical company developing product candidates intended to address unmet medical needs in areas of inflammation, oncology, and biodefense. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing a first-in-class photo-dynamic therapy (SGX301) utilizing 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 (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, VeloThrax™, our anthrax vaccine candidate, OrbeShield™, our GI acute radiation syndrome (“GI ARS”) therapeutic candidate and SGX943, our melioidosis therapeutic candidate. The development of our vaccine programs is supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government

contract funding. With the recently awarded government contract 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. Additionally, we have entered into a global and exclusive channel collaboration with Intrexon Corporation (“Intrexon”) through which we intend to develop and commercialize a human monoclonal antibody therapy (SGX101) to treat melioidosis.

An outline for our business strategy follows:

Conduct a Phase 3 clinical trial for SGX301 for the treatment of CTCL;
Conduct a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;

Initiate a Phase 3 clinical trial of oral BDP, known as SGX203, for the treatment of pediatric Crohn’s disease;
 Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis;
 Develop RiVax™ and VeloThrax™ in combination with our ThermoVax™ technology, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
 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;
 Acquire or in-license new clinical-stage compounds for development; and
 Explore other business development and merger/acquisition strategies, an example of which is our collaboration with Intrexon.

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 ($p \leq 0.04$) compared to placebo; Phase 3 clinical trial planned for the first 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 data expected in the second half of 2015
SGX203**	Pediatric Crohn's disease	Phase 1/2 clinical trial completed in June 2013, data pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed; Phase 3 clinical trial planned for the second half of 2015, with data expected in the first half of 2017 Phase 1/2 clinical trial complete;
SGX201**	Acute Radiation Enteritis	safety and preliminary efficacy demonstrated; Phase 2 trial planned for the second half of 2015, with data expected in the second half of 2016

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 2015
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2016
OrbeShield™	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943/SGX101	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 ($p\text{-value} \leq 0.04$) improvement with topical hypericin treatment whereas the placebo was ineffective: 58.3% compared to 8.3%, respectively.

SGX301 has received orphan drug designation as well as Fast Track designation from the U.S. 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 SGX942 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.

We anticipate initiating a Phase 3 clinical study of SGX301 in the treatment of CTCL in the first half of 2015.

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.

SGX94

SGX94 is an innate defense regulator (“IDR”) that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing.

SGX94 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.

SGX94 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. SGX94 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. SGX94 is the subject of an open Investigational New Drug (“IND”) application which has been cleared by the FDA. We believe that market opportunities for SGX94 include mucositis, acute methicillin resistant *Staphylococcus aureus* (MRSA) bacterial infections, acinetobacter, melioidosis, acute radiation syndrome and as a vaccine adjuvant, 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 platform, SGX94, targeting the treatment of oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received “Fast Track” designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients

from the FDA in the first half of 2013.

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 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

About Oral Mucositis

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

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

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

Oral BDP

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

Based on its pharmacological characteristics, oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We are planning to pursue development programs 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 designations for relevant indications as appropriate in both the U.S. and Europe. An orphan drug designation in the U.S. enables seven years of market exclusivity upon approval, while the EU approval provides with ten years of market exclusivity.

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 2015.

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.

About 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 are currently working with our Radiation Enteritis medical advisory board in pursuing additional funding from the NIH 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.

About 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-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 in turn 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 being 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-adsorbed ricin toxin vaccine, RiVax™ and our aluminum-adsorbed 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.

We intend to seek out potential partnerships with companies marketing FDA/ex-U.S. health authority approved 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 has the potential to allow for the development of multivalent vaccines (e.g., combination ricin-anthrax vaccine).

RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine candidate being developed to protect against exposure to ricin toxin, and if approved, would be the first ricin vaccine. The immunogen in RiVax™ induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin. RiVax™ has demonstrated statistically significant ($p < 0.001$) 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 Epub ahead of print March 9, 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.

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 also 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 ricin vaccine, nor is there a known antidote for ricin toxin exposure.

VeloThrax™ – Anthrax Vaccine

VeloThrax™ is our proprietary vaccine candidate based on a recombinant protective antigen (“rPA”) derivative intended for use against anthrax. We have entered into an exclusive license option with Harvard College to license VeloThrax™ (also known as DNI for dominant negative inhibitor) for a vaccine directed at the prevention of anthrax infection of humans. VeloThrax™ is a translocation-deficient mutant of a protective antigen with double mutations of K397D and D425K that impede the conformational changes necessary for endosomal membrane translocation into the cell cytoplasm. In the absence of that protective antigen translocation step, anthrax toxin trafficking and function cease. We believe that VeloThrax™ is also considered a more immunogenic candidate than native rPA. This apparent increase in immunogenicity suggests that the DNI rPA is processed and presented to the immune system more efficiently by cellular antigen processing pathways, which is consistent with known properties of the molecule.

DNI versions of rPA such as VeloThrax™ are also capable of inducing antibodies that neutralize the activity of the anthrax toxin complex. Unlike fully-functional rPA, VeloThrax™ might be given to a patient post-exposure without risk of enhancing intoxication during an infection, although clinical tests involving intravenous administration of potentially therapeutic levels of DNI rPA resulted in serious adverse events and so further development of this product as a therapeutic biological for blocking the effects of infection by *B. anthracis* was discontinued. Our studies of VeloThrax™ will be at a dose 1,000 times lower than the dose previously tested for an intramuscular or intradermal vaccine.

We believe that VeloThrax™'s greater immunogenicity could lead to a vaccine that can be administered in the fewest possible doses to induce the highest level of toxin neutralizing antibodies. Utilizing ThermoVax™, we believe that we will be able to develop VeloThrax™ into a vaccine with an improved stability profile, an issue that has proven challenging in the development of other anthrax vaccines. Extended stability at ambient temperatures would be a significant improvement for stockpiled vaccines and one which is not expected from conventional vaccines. Further, a large-scale, current Good Manufacturing Practice ("cGMP") production methodology has already been completed. Assuming long-term stability can be met; VeloThrax™ could be stockpiled for general prophylactic as well as a post exposure use.

The overall objective of the VeloThrax™ program is to rapidly and efficiently develop a next generation anthrax vaccine which combines a well-established, safe and relatively low risk vaccine development and dosing approach with targeted, proven innovative strategies. We expect that VeloThrax™ will combine a combination of a stable, readily manufactured mutant rPA subunit antigen with next generation, clinically compatible adjuvants which have been demonstrated to enhance potency and reduce the time and number of vaccine doses required to achieve protective titer using a variety of vaccine antigens. We believe that VeloThrax™ has the potential to provide the Public Health Emergency Medical Countermeasures Enterprise ("PHEMCE") and the DoD with a safe and stable alternative to the existing licensed anthrax vaccine product. We also intend to adapt newly developed glassification technology (initially developed under an ongoing NIAID grant to stabilize exceptionally unstable ricin toxin/adjuvant formulations) to enable a thermostable, dried, single vial, pre-formulated adjuvanted rPA vaccine which is suitable for both long term storage and field use without typical cold chain constraints.

Assuming development efforts are successful for VeloThrax™, we believe potential government procurement contract(s) could reach \$500 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.

Anthrax

Anthrax is an acute infectious disease that is easily transmitted to humans by environmentally durable spores that are produced by *Bacillus anthracis*. Because the spores are robust and contagious, anthrax is considered a Category A bioterror threat. Anthrax infection can occur in three forms: cutaneous (skin), inhalation, and gastrointestinal. Inhaled spores can cause a rapidly progressing form of anthrax since the spores are transported to lymph nodes near the lungs where they germinate, releasing vegetative bacteria into the bloodstream. Bacteria synthesize a complex series of toxin components that make up anthrax toxin, resulting in overwhelming toxemia that causes shock and organ failure. Treatment of anthrax involves long-term antibiotic therapy, since ungerminated spores can lie dormant in the lungs for up to 60 days. Only a few inhaled spores can cause inhalational anthrax. Once the toxin has entered the bloodstream, antibiotics are ineffective, and only toxin-specific therapy is effective. Passively transferred antibodies can neutralize anthrax toxins and can be used post-exposure in conjunction with antibiotics. Because of the long residence time of spores in the lung, it is possible to vaccinate post-exposure, but the onset of neutralizing antibodies must occur during the period of antibiotic therapy.

OrbeShield™ – for Treating GI ARS

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 ARS

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/SGX101– for Treating Melioidosis

SGX943 uses the same active ingredient as SGX94 and is being developed in preclinical studies as a potential treatment for melioidosis. Because SGX943 directly targets the innate immune system (and does not attempt to kill the bacteria directly), we believe it is particularly relevant for antibiotic-resistant bacteria. The bacteria which causes melioidosis, *Burkholderia pseudomallei*, is known to be resistant to most antibiotics and to require prolonged treatment with the few antibiotics that do work. In February 2014, we were awarded a one-year NIAID SBIR grant 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 ($p < 0.001$).

SGX101 is a human monoclonal antibody therapy being developed in preclinical studies as a potential treatment of melioidosis using Intrexon's advanced human antibody discovery, isolation, and production technologies. As data becomes available from this work, we intend to pursue grant funding to support further development of this product candidate.

Melioidosis

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

Bp infection (melioidosis) is a major public health concern in the endemic regions of Southeast Asia and Northern Australia. In Northeast Thailand, which has a high 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 these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. We evaluate these estimates and judgments on an on-going basis.

Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 730, *Research and Development*. Based on this consideration, we capitalized payments made to legal firms that are engaged in filing and protecting rights to intellectual property rights for our current product candidates in both the domestic and international markets. We believe that patent rights are one of our most valuable assets. Patents and patent applications are 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, maintain and perhaps extending the lives of the patents. We capitalize such costs and amortize intangibles 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, 2015. Accordingly, the estimates 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, accounts receivable, accounts payable and accrued expenses 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.

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, stock 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.

Revenue Recognition

Principally our revenues are generated from government contracts and grants. Recording of revenue is applied in accordance with FASB ASC 605, *Revenue Recognition*, ASC 605-25 and/or ASU, 2009-13, *Revenue Recognition – Multiple Element Arrangements*. 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. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant.

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 2015 and 2014.

Share-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of issuance. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees vest 25% on the grant date, then 25% each subsequent year for a period of three years. Stock options vest over each three-month period from the date of issuance to the end of the three year period. These options have a ten year life for as long as the individuals remain employees or directors. In general, when an employee or director terminates their position, the options will expire within three months, unless otherwise extended by the Board.

From time to time, we issue restricted shares of our common stock to vendors and consultants as compensation for services performed. Share-based compensation expense recognized during the period is based on the fair value of the portion of share-based payment awards that is ultimately expected to vest during the period. Typically these instruments vest upon issuance and, therefore, the entire stock compensation expense is recognized upon issuance to the vendors and/or consultants.

We determine share-based compensation expense for options, warrants and shares of common stock granted to non-employees 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. Share-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

Material Changes in Results of Operations

Three Months Ended March 31, 2015 Compared to March 31, 2014

For the three months ended March 31, 2015, we had a net loss of \$4,569,322 as compared to a net loss of \$3,331,708 for same period in the prior year, representing an increase in the net loss of \$1,237,614, or 37%. Included in the net loss for March 31, 2015 is a non-cash charge of \$3,011,616 as compared to \$1,742,090 for the same period in the prior year representing the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering.

For the three months ended March 31, 2015, revenues relate to government contracts and grants awarded in support of our development in OrbeShield™ in GI ARS and RiVax™. We had revenues of \$816,286 as compared to \$910,597 for the same period in the prior year, representing a decrease of \$94,311, or 10%. The decrease in revenues was a result of our ThermoVax™ grant expiring during the fourth quarter of 2014.

We incurred costs related to those revenues for the three months ended March 31, 2015 and 2014 of \$527,399 and \$628,981, respectively, representing a decrease of \$101,582, or 16%. These costs relate to allocated employee costs and payments due to subcontractors in connection with research performed pursuant to the contracts and grants.

Edgar Filing: SOLIGENIX, INC. - Form 10-Q

Our gross profit for the three months ended March 31, 2015 was \$288,887, as compared to \$281,616 for the same period in 2014, representing an increase of \$7,271, or 3%.

Research and development spending was \$1,029,884 for the three months ended March 31, 2015 as compared to \$1,030,621 for the same period in 2014, representing a nominal decrease.

General and administrative expenses were \$817,270 for the three months ended March 31, 2015, as compared to \$840,904 for the same period in 2014, representing a nominal decrease.

Other income (expense) for the three months ended March 31, 2015 was \$(3,011,055) as compared to \$(1,741,799) for the same period in 2014, representing an increase of \$1,269,256, or 73%. The increase in expense is primarily attributable to a greater non-cash charge in 2015 compared to 2014 for the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering.

Financial Condition

Cash and Working Capital

As of March 31, 2015, we had cash and cash equivalents of \$5,012,605 as compared to \$5,525,094 as of December 31, 2014, representing a decrease of \$512,489 or 9%. As of March 31, 2015, we had working capital of \$2,913,440 as compared to working capital of \$3,174,214 as of December 31, 2014, which excludes a non-cash warrant liability of \$5,152,367 and \$3,789,562, respectively, representing a decrease of \$260,777, or 8%. This decrease is primarily related to expenditures to support the Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer.

Based on the Company's current rate of cash outflows, cash on hand, proceeds from government contract and grant programs, proceeds available from the Lincoln Park equity line and proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures for at least the next twelve months.

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

We have up to \$50.5 million in active contract and grant funding still available to support our associated research programs in 2015 and beyond. We plan to submit additional contract and grant applications for further support of these programs with various funding agencies.

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

We will pursue NOL sales in the State of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of \$616,872 in proceeds from the sale of NJ NOL in 2014, we expect to participate in the program during 2015 and beyond as the program is available.

We have a \$10.6 million equity facility, with Lincoln Park, through October 2016, of which approximately \$9.3 million is available.

We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Expenditures

Under our budget and based upon our existing product development agreements, license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately \$16.1 million before any grant reimbursements, of which \$5.7 million relates to the BioTherapeutics business and \$10.4 million relates to the Vaccines/BioDefense business. We anticipate contract and grant revenues in the next 12 months of approximately \$10.4 million to offset research and development expenses in the Vaccines/BioDefense business segment.

The table below details our costs for research and development by program and amounts reimbursed for the three months ended March 31:

	2015	2014	
<i>Research & Development Expenses</i>			
Oral BDP	\$-	\$271,438	
RiVax™ and ThermoVax™ Vaccines	192,923	177,318	
SGX94	513,442	495,294	
SGX943/101	7,227	-	
SGX301	247,396	-	
Other	68,896	86,571	
Total	\$1,029,884	\$1,030,621	
<i>Reimbursed under Government Contracts and Grants</i>			
OrbeShield™		294,313	460,139
RiVax™ and ThermoVax™ Vaccines		165,814	168,842
Other		67,272	-
Total		\$527,399	\$628,981
Grand Total		\$1,557,283	\$1,659,602

Contractual Obligations

We have commitments of approximately \$500,000 as of March 31, 2015 relating to several licensing agreements with consultants and universities. Additionally, we have collaboration and license agreements, which upon clinical or commercialization success may require the payment of milestones of up to \$7.9 million and/or royalties up to 6% of net sales of covered products, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

In December 2014, we entered into a lease agreement through May 31, 2018 for existing and expanded office space. The rent for the first 12 months 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 thereafter to approximately \$12,460 per month, or approximately \$21.13 per square foot for the remainder of the lease.

On September 3, 2014, we entered into an asset purchase agreement with Hy Biopharma, Inc. (“Hy Biopharma”) pursuant to which we acquired certain intangible assets, properties and rights of Hy Biopharma related to the development of Hy BioPharma’s synthetic hypericin product. As consideration for the assets acquired, we paid \$250,000 in cash and issued 1,849,113 shares of common stock with a fair value of \$3,750,000. These amounts were

charged to research and development expense during the third quarter of 2014 as the assets will be used in our research and development activities and do not have alternative future use pursuant to generally accepted accounting principles in the United States. Provided all future success-oriented milestones are attained, we will be required to make payments of up to \$10.0 million, if and when achieved. Payments will be payable in restricted securities of the Company not to exceed 19.9% ownership of its outstanding stock.

On April 27, 2013, we entered into an exclusive channel collaboration agreement (the “Channel Agreement”) with Intrexon to use Intrexon’s advanced human antibody discovery, isolation and production technologies for the development of human monoclonal antibody therapies for a new biodefense application targeting melioidosis. The Channel Agreement grants an exclusive worldwide license to use specified patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale and offer for sale of products for the treatment of melioidosis through the use of exogenously produced human recombinant monoclonal antibodies. The Channel Agreement, upon clinical or commercialization success, may require the payment of certain milestones payments up to \$7 million, if and when achieved.

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

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

Year	Research and Development	Property and Other Leases	Total
April 1 through December 31, 2015	\$ 100,000	\$99,000	\$ 199,000
2015	100,000	157,000	257,000
2016	100,000	152,000	252,000
2017	100,000	52,000	152,000
2018	100,000	-	100,000
Total	\$ 500,000	\$460,000	\$ 960,000

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

ITEM 4 - CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are the Company's controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the possible controls and procedures.

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, our management, including our principal executive officer and principal financial officer, has concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Controls

There was no change in our internal control over financial reporting identified in connection with the evaluation of such internal controls that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II – OTHER INFORMATION.

ITEM 1A – RISK FACTORS

We have identified no additional risk factors other than those included in Part I, Item 1A of our Form 10-K for the fiscal year ended December 31, 2014. Readers are urged to carefully review our risk factors because they may cause our results to differ from the "forward-looking" statements made in this report. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations. We do not undertake to update any of the "forward-looking" statements or to announce the results of any revisions to these "forward-looking" statements, except as required by law.

ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On January 7, 2015, the Company issued 6,000 shares of common stock to a vendor as partial consideration for services performed. The per share issuing price of the Company's common stock was \$1.21.

On January 12, 2015, the Company issued 10,000 shares of common stock to a vendor for as partial consideration for services performed. The per share issuing price of the Company's common stock was \$1.21.

On February 19, 2015, the Company issued 50,000 shares of common stock to a vendor for partial consideration for services performed. The per share issuing price of the Company's common stock on February 19, 2015 was \$1.64.

The Company believes the issuance of these shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving any public offering. The recipients of the securities in each of these transactions represented their intentions to acquire securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. The recipients either have enough knowledge and experience in finance and business matters to be able to evaluate the risks and merits of the investment or are able to bear the investment's economic risk. All recipients either received or had adequate access, through their business or other relationships with the Company, to information about the Company.

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOLIGENIX, INC.

May 14, 2015 By/s/ Christopher J. Schaber
Christopher J. Schaber, PhD

President and Chief Executive Officer

(Principal Executive Officer)

May 14, 2015 By/s/ Joseph M. Warusz
Joseph M. Warusz, CPA

Vice President, Finance and Acting Chief Financial Officer (Principal Financial and Accounting Officer)

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
31.1	Certification of Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
31.2	Certification of Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.