SOLIGENIX, INC.
Form 10-Q
May 12, 2014

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2014

or

o 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	41-1505029
(State or other jurisdiction of incorporation or organization)	(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 x No o

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 x No o

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 o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company x

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

As of May 05, 2014, 19,972,234 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

SOLIGENIX, INC.

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PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc. and Subsidiaries
Consolidated Balance Sheets

	March 31, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$5,606,850	$5,856,242
Contracts and grants receivable	694,346	867,086
Taxes receivable	-	750,356
Prepaid expenses	97,620	135,391
Total current assets	6,398,816	7,609,075
Office furniture and equipment, net	36,357	23,868
Intangible assets, net	577,800	632,512
Total assets	$7,012,973	$8,265,455
Liabilities and shareholders' deficiency		
Current liabilities:		
Accounts payable	$1,552,629	$1,520,290
Warrant liability	9,521,312	8,281,247
Accrued compensation	45,309	233,739
Total current liabilities	11,119,250	10,035,276
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; 19,852,260 shares and 19,626,439 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	19,852	19,626
Additional paid-in capital	131,544,956	130,549,930
Accumulated deficit	(135,671,085)	(132,339,377)
Total shareholders' deficiency	(4,106,277)	(1,769,821)
Total liabilities and shareholders' deficiency	$7,012,973	$8,265,455

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, 2014 and 2013
(Unaudited)

	Three Months Ended March 31,	
	2014	2013
Revenues:		
Grant revenue	$ 244,290	$ 900,354
Contract revenue	666,307	-
Total revenues	910,597	900,354
Cost of revenues	(628,981)	(743,657)
Gross profit	281,616	156,697
Operating expenses:		
Research and development	1,030,621	756,653
General and administrative	840,904	487,941
Total operating expenses	1,871,525	1,244,594
Loss from operations	(1,589,909)	(1,087,897)
Other income (expense):		
Change in fair value of warrant liability	$ (1,742,090)	
Interest income	291	483
Total other income (expense)	(1,741,799)	483
Net loss	$ (3,331,708)	$ (1,087,414)
Basic and diluted net loss per share	$ (0.17)	$ (0.10)
Basic and diluted weighted average common shares outstanding	19,739,470	11,180,739

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Changes in Shareholders' Deficiency
For the Three Months Ended March 31, 2014
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2013	19,626,439	$19,626	$130,549,930	$(132,339,377)	$(1,769,821)
Issuance of common stock pursuant to Lincoln Park Equity Line	76,932	77	158,173	-	158,250
Issuance of restricted common stock to vendors	71,000	71	153,469	-	153,540
Reclassification of warrant liability upon partial exercise of warrants issued in unit offering	-	-	502,025	-	502,025
Fair value of common stock warrants issued to vendors	-	-	4,775	-	4,775
Issuance of common stock from cashless exercise of warrants	77,889	78	(78)	-	-
Stock-based compensation expense	-	-	176,662	-	176,662
Net loss	-	-	-	(3,331,708)	(3,331,708)
Balance, March 31, 2014	19,852,260	19,852	$131,544,956	$(135,671,085)	$(4,106,277)

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)

	2014	2013
Operating activities:		
Net loss	$(3,331,708)	$(1,087,414)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	62,087	56,498
Restricted common stock issued to vendors	153,540	32,888
Warrants issued to vendors	4,775	-
Stock-based compensation	176,662	79,492
Change in fair value of warrant liability	1,742,090	-
Change in operating assets and liabilities:		
Grants receivable	172,740	(317,544)
Taxes receivable	750,356	-
Prepaid expenses	37,771	(30,085)
Accounts payable	32,338	527,238
Accrued compensation	(188,430)	(5,432)
Total adjustments	2,943,929	343,055
Net cash used in operating activities	(387,779)	(744,359)
Investing activities		
Purchases of fixed assets	(19,863)	-
Net cash used in investing activities	(19,863)	-
Financing Activities:		
Net proceeds from issuance of common stock pursuant to the equity line	158,250	-
Net cash provided by financing activities	158,250	-
Net decrease in cash and cash equivalents	(249,392)	(744,359)
Cash and cash equivalents at beginning of period	5,856,242	3,356,380
Cash and cash equivalents at end of period	$5,606,850	$2,612,021
Supplemental disclosure of non cash investing and financing activities:		
Reclassification of warrant liability to additional paid in capital upon partial exercise of warrants issued in unit offering	$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 clinical stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat the life-threatening side effects of cancer treatments and serious gastrointestinal diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense.

The Company's BioTherapeutics business segment is developing 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), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing its novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis.

The Vaccines/BioDefense business segment includes RiVax™, a ricin toxin vaccine, VeloThrax™, an anthrax vaccine, and OrbeShield™, a gastrointestinal acute radiation syndrome ("GI ARS") therapeutic and SGX943, a melioidosis therapeutic. The advanced development of these programs will be supported by existing and on-going government grants and contracts, which include a National Institutes of Health ("NIH") grant for the heat stabilization technology ThermoVax™ supporting the vaccine programs, as well as contracts with the Biomedical Advanced Research and Development Authority ("BARDA") and NIAID for 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 three grants primarily from 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 Adsministration (the "FDA") regulations, litigation, and product liability. Results for the quarter ended March 31, 2014 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of March 31, 2014, the Company had cash and cash equivalents of $5,606,850 as compared to $5,856,242 as of December 31, 2013, representing a decrease of $249,392 or 4%. As of March 31, 2014, the Company had working capital of $4,800,878 as compared to working capital of $5,855,046 as of December 31, 2013, which excludes a non-cash warrant liability of $9,521,312 and $8,281,247, respectively, representing a decrease of $1,054,168 or 18%. 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 plan can be outlined as follows:

- Conduct a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Initiate a Phase 2/3 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, prevention of acute radiation syndrome, and treatment of chronic GVHD;
- Develop RiVax™ and VeloThrax™ in combination with its proprietary vaccine heat stabilization technology, known as ThermoVax™, 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 its BioTherapeutics and Vaccine/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 $32.3 million in active contract and grant funding still available to support its associated research programs through 2014 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/or collaboration partners and expects to continue to do so for the foreseeable future.
- The Company will pursue Net Operating Loss ("NOLs") sales in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt, in January 2014, of $750,356 in proceeds pursuant to NOLs sales in 2013, the Company expects to participate in the program during 2014 and beyond;
- The Company has a $10.0 million equity facility, with Lincoln Park through October 2016, of which approximately $9.8 million is available; and
- The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company is currently evaluating additional equity financing opportunities 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.

Grants and Contracts Receivable

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

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 industrial 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 over their expected useful life – generally a period of 11 to 16 years.

The Company did not capitalize any patent related costs during the quarters ended March 31, 2014 and 2013.

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 quarters ended March 31, 2014 and 2013.

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, 2014. 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 offering were accounted for as derivatives. See Note 4, Warrant Liabilities.

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, ASC 605-25 and/or Accounting Standard Update, 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 grants, plus a facilities and administrative rate that provides funding for overhead expenses and management fee. 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 2014 and 2013.

Stock-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% immediately as of 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. Stock-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.

Stock 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-employee directors is amortized as the options vest.

The fair value of options issued during the three months ended March 31, 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 of 133% - 135% ;
- Forfeitures at a rate of 12%; and

- Risk free interest rates of 1.11% - 1.33%.

The Company did not issue issue any options during the three months ended March 31, 2013.

The fair value of each option grant was estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's 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, 2014 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 2014 and 2013. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at March 31, 2014 and 2013. Tax years beginning in 2010 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. No options and warrants were included in the 2014 and 2013 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses on options and warrants for which the strike price exceeds the quoted market value at period end.

	Three Months Ended March 31,					
	2014			2013		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	$(3,331,708)	19,739,470	$(0.17)	$(1,087,414)	11,180,739	$(0.10)

Shares issuable upon the exercise of options and warrants outstanding at March 31, 2014 and 2013 were 2,127,699 and 1,454,755 and 6,808,324 and 2,843,338. The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2014 was $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
March 31, 2014				
Licenses	6.5	$462,234	$ 285,974	$176,260
Patents	2.4	1,893,185	1,491,645	401,540
Total	3.2	$2,355,419	$ 1,777,619	$577,800
December 31, 2013				
Licenses	6.72	$462,234	$ 279,258	$182,976
Patents	2.6	1,893,185	1,443,649	449,536
Total	3.4	$2,355,419	$ 1,722,907	$632,512

Amortization expense was $54,712 and $55,043 for the three months ended March 31, 2014 and 2013, respectively.

Based on the balance of licenses and patents at March 31, 2014, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
April 1 through December 31,2014	$ 168,100
2015	$ 172,500
2016	$ 61,800
2017	$ 61,800
2018	$ 20,800

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

Note 4. Warrant Liabilities

Warrants issued in connection with the Company's 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.

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

The Company recognized an initial warrant liability for the warrants issued in connection with the registered public offering completed in June 2013 totaling $4,827,788, which was based on the June 25, 2013 closing price of a share of the Company's common stock as reported on OTC Markets of $0.96. On January 21, 2014, 250,000 warrants were exercised. The fair value of the warrants exercised, or $502,025, was reclassified from Warrant liability to Additional paid-in capital. On March 31, 2014, the closing price of the Company's common stock as reported on OTC Markets was $2.24. Due to the fluctuations in the market value of the Company's common stock from December 31, 2013 through March 31, 2014, the Company recognized a non-cash charge of $1,742,090 for the change in the fair value of the warrant liability for the three months ended March 31, 2014.

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

	December 31, 2013	January 22, 2014	March 31, 2014
Number of shares underlying the warrants	5,309,438	5,309,438	5,059,438
Exercise price	$1.65	$1.65	$1.65
Volatility	135 %	135 %	133 %
Risk-free interest rate	1.75 %	1.30 %	1.32 %
Expected dividend yield	0	0	0
Expected warrant life (years)	4.5	4.42	4.25
Stock Price	$1.80	$2.29	$2.24

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, 2014 for the financial liability categorized as Level 3 as of March 31, 2014.

	December 31, 2013	Decrease from Warrants Exercised in 2014	Increase in Fair Value	March 31, 2014
Warrant liability	$ 8,281,247	$ (502,025)	$ 1,742,090	$ 9,521,312

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Note 5. Income Taxes

The Company had NOLs at December 31, 2013 of approximately $80,793,000 for federal tax purposes and approximately $5,599,000 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 until 2033. In addition, the Company had $2,986,000 of various tax credits that expire from 2014 to 2033. 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 carryforwards 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 possible that the utilization of the NOLs, could 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, 2014 and 2013 due to losses incurred and the recognition of full valuation allowances 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, 2014, the Company issued the following shares of common stock:

- In January 2014, the Company issued 77,889 shares of common stock in connection with the cashless exercise of 250,000 stock warrants;
- In March 2014, the Company issued 76,932 shares of common stock pursuant to the Lincoln Park facility; and
- In three separate transaction, the Company issued 71,000 shares of common stock as partial consideration for services performed.

Note 7. Commitments and Contingencies

The Company has commitments of approximately $344,000 as of March 31, 2014 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.

On April 27, 2013, the Company entered into an exclusive channel collaboration agreement with Intrexon (the "Channel Agreement") 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 up to $7 million, if and when achieved.

On February 7, 2012, the Company entered into a lease agreement through March 31, 2015 for existing office space. The rent for the first 12 months is approximately $8,000 per month, or approximately $18.25 per square foot. This rent increases to approximately $8,310 per month, or approximately $19.00 per square foot, for the remaining 24 months.

In February 2007, the Company's Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by the its Board of Directors whereby, directly or indirectly, a majority of the its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 50,000 common shares to Dr. Schaber and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes its obligation to issue such shares if such event occurs.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment.

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, 2014	$ 44,000	$81,000	$125,000
2015	75,000	33,000	108,000
2016	75,000	9,000	84,000
2017	75,000	2,000	77,000
2018	75,000	-	75,000
Total	$ 344,000	$125,000	$469,000

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,	
	2014	2013
Contract/Grant Revenue		
Vaccines/BioDefense	$877,045	$829,849
BioTherapeutics	33,552	70,505
Total	$910,597	$900,354
Income/(Loss) from Operations		
Vaccines/BioDefense	$139,404	$(30,995)
BioTherapeutics	(1,035,591)	(457,625)
Corporate	(693,722)	(599,277)
Total	$(1,589,909)	$(1,087,897)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$9,935	$27,667
BioTherapeutics	49,939	28,395
Corporate	2,213	436
Total	$62,087	$56,498
Interest Income		
Corporate	$291	$483
Stock-Based Compensation		
Vaccines/BioDefense	$10,450	$11,121
BioTherapeutics	76,121	21,036
Corporate	90,091	47,335
Total	$176,662	$79,492

	As of March 31, 2014	As of December 31, 2013
Identifiable Assets		
Vaccines/BioDefense	$948,567	$1,870,414
BioTherapeutics	339,502	386,721
Corporate	5,724,904	6,008,320
Total	$7,012,973	$8,265,455

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, 2013. 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 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. Securites and Exchage 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 Company makes in this report and our other reports filed with the U.S. Securites and Exchage Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Overview:

Our Business Overview

We are a clinical stage biopharmaceutical company that is focused on developing products to treat serious inflammatory diseases where there remains an unmet medical need as well as developing several biodefense vaccines and therapeutics. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing 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), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, OrbeShield™, our GI acute radiation syndrome ("GI ARS") therapeutic and SGX943, our melioidosis therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding. With the recently awarded government contracts from the Biomedical Advanced Research and Development Authority ("BARDA") and the National Institute of Allergy and Infectious Diseases ("NIAID"), we will attempt to advance the development of OrbeShield™ for the treatment of GI ARS. Additionally, we 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 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Initiate a Phase 2/3 clinical trial of oral BDP, known as SGX203, for the treatment of pediatric Crohn's disease;

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- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, and treatment of chronic graft-versus-host disease ("GI GVHD");
- Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology, known as ThermoVax™, 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.

We were incorporated in Delaware in 1987 under the name Immunotherapuetics Inc. In 1987, the Company merged with Biological Therapeutics, Inc., a North Dakota corporation, with the Company being the surviving corporation. The Company changed its 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 the products that we are currently developing:

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
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 2014
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical trial completed in June 2013, data pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed; Phase 2/3 clinical trial planned for the second half of 2014, with data expected in the second half of 2015
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated; Phase 2 trial planned for the second half of 2014, with data expected in the second half of 2015
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial initiated in the second half of 2013, with data expected in the second half of 2014

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 2 trial planned for the first half of 2015
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2015
OrbeShield™	Therapeutic against GI ARS	Pre-clinical program initiated
SGX943/SGX101	Melioidosis	Pre-clinical

** Contingent upon continued government contract and grant funding

BioTherapeutics Overview

SGX94

In December 2012, we acquired a drug technology, we refer to as SGX94, representing what we believe is a novel approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. As part of the acquisition, we acquired all rights, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94. We also assumed a license agreement with the University of British Columbia (“UBC”) to advance the research and development of the SGX94 technology. The license agreement with UBC provides us with exclusive worldwide rights to manufacture, distribute, market sell and/or license or sublicense products derived or developed from this technology.

SGX94 is the research name for the active ingredient in SGX942, which is the research name for the finished drug product being studied in oral mucositis. It is 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 provide 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 are 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.

We have a strong worldwide IP position on SGX94 and related analogs including composition of matter. SGX94 was developed pursuant to discoveries made by Professors B. Brett Finlay and Robert Hancock of the UBC, Canada and approximately $40 million has been invested towards its development to date, inclusive of government grants.

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 showed a strong safety profile 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. Market opportunities include, but are not limited to, mucositis, acute bacterial skin and skin structure 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

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. 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. 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 New Drug Application ("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, which implies an abbreviated review time of six months. In April 2014, we were awarded a one-year National Institute of Dental and Craniofacial Research (NIDCR) Small Business Innovation and Research ("SBIR") grant award of approximately $200,000 to support our Phase 2 clinical study.

We believe the potential worldwide market for SGX942 is in excess of $500 million for all applications, including oral mucositis.

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 gastro-intestinal 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 now 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 (>80% incidence of severe mucositis) and is common (40-100% incidence) 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 gastrointestinal 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 have an issued U.S. patent 8,263,582 claiming the use of oral BDP as a method of treating inflammatory disorders of the gastrointestinal tract, including Crohn’s disease, and an issued U.S. patent 6,096,731 claiming the use of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD following hematopoietic cell transplantation, as well as GVHD which also occurs following organ allograft transplantation. We also have European Patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract. We are planning to pursue development programs in the treatment of pediatric Crohn’s disease, acute radiation enteritis, chronic GI GVHD 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 believe the potential worldwide market for oral BDP is in excess of $500 million for all GI applications, namely, pediatric Crohn’s disease, radiation enteritis, GI ARS, and chronic GI GVHD.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, oral BDP would benefit from orphan drug designations in the U.S. and in Europe. Orphan drug designations provide for 7 and 10 years of market exclusivity upon approval in the U.S. and Europe, respectively.

SGX203 – for Treating Pediatric Crohn’s Disease

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

About Pediatric Crohn's Disease

Crohn's disease is an ongoing disorder that 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 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 (~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. 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 ("NCI") Common Terminology Criteria for Adverse Events for selected gastrointestinal events. In addition, the incidence of diarrhea was lower than that seen in recent published historical control data in this patient population. This program was supported in part by a $500,000 two-year SBIR grant awarded by the NCI . We are currently working with our Radiation Enteritis medical advisory board to determine potential next steps forward with the clinical development program, as well as pursuing continued grant funding to advance the program .

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

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 2-6 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.

orBec® - for Treating Chronic GI GVHD

orBec® is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP to treat the gastrointestinal manifestation of chronic GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs such as prednisone to treat chronic GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. 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. orBec® has been awarded orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD. In September 2012, we received a $300,000 two-year SBIR grant awarded by the NCI to support a Phase 2 study for the treatment of chronic GI GVHD.

About Chronic GVHD

GVHD is a major complication of allogeneic hematopoietic cell transplantation. GVHD is an inflammatory disease initiated by T cells in the donor graft that recognize histocompatibility and other tissue antigens of the host, and is mediated by a variety of effector cells and inflammatory cytokines. GVHD presents in both acute and chronic forms. The symptoms of chronic GVHD typically present at between 100 days and three years post-transplant.

Chronic GVHD has features resembling autoimmune and other immunologic disorders such as scleroderma, Sjögren syndrome, primary biliary cirrhosis, wasting syndrome, bronchiolitis obliterans, immune cytopenias and chronic immunodeficiency. The manifestations of chronic GVHD may be restricted to a single organ or tissue or may be widespread. Chronic GVHD can lead to debilitating consequences, e.g., joint contractures, loss of sight, end-stage lung disease, or mortality resulting from profound chronic immune suppression leading to recurrent or life-threatening infections.

Treatment of chronic GVHD is a challenge because it can be refractory to frontline immunosuppression. High-dose systemic corticosteroids are used with some success but carry significant toxicity. The risks of prolonged immunosuppression include local and disseminated infections, Epstein-Barr virus associated lymphoproliferative disease, hypothalamic-pituitary-adrenal (“HPA”) axis suppression, myopathy, glucose intolerance, neuropsychiatric disease and bone demineralization.

We estimate, based upon our review of published studies and reports and an interpolation of data on the incidence of chronic GVHD, there to be 6,000 patients annually in the U.S., with a comparable number in Europe that suffer from chronic GVHD.

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, a meaningful proportion of vaccine doses globally are wasted 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. The savings realized from the elimination of cold chain costs and related product losses would in turn significantly increase the profitability of vaccine products. Elimination of the cold chain would also 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 is 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-adjuvanted ricin toxin vaccine, RiVax™, made under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the ricin A chain, the immunogenic compound of the vaccine. 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. Confirmatory results have extended the stability to one year when the vaccine is kept at 40 degrees C. 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.

Near term progress with ThermoVax™ will allow us 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. ThermoVax™ will further enable Soligenix to expand its vaccine development expertise beyond biodefense into the infectious disease space and also has the potential to allow for the development of multivalent vaccines (e.g., combination ricin-anthrax vaccine).

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

RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first ricin vaccine. With RiVax™, we are a world leader in ricin toxin vaccine research. 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. Two Phase 1 human clinical trials have been completed. 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 the University of Texas Southwestern Medical Center ("UTSW") where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. Soligenix and UTSW have collectively received approximately $25 million in grant funding from the NIH for RiVax™. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies anticipated to 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, sponsored by UTSW, evaluated a more potent formulation of RiVax™ that contained an aluminum adjuvant (Alum), was completed in September 2012. 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.

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

About Ricin Toxin

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

2013, letters addressed to the President, a U.S. Senator and a judge tested positive for ricin.

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

In January of 2012, a Request for Information ("RFI") was issued by the Chemical Biological Medical Systems – Joint Vaccine Acquisition Program of the Department of Defense ("DoD"). This RFI was titled "Development of a Ricin Toxin Vaccine to FDA Approval", and marks the first time any agency of the U.S. government has specifically indicated an interest in development of a vaccine against ricin toxin. We intend to pursue this avenue of funding to the fullest extent.

VeloThrax™ – Anthrax Vaccine

VeloThrax™ is our newly acquired proprietary vaccine based on a recombinant Protective Antigen ("rPA") derivative intended for use against anthrax. Soligenix has 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 PA 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 PA translocation step, anthrax toxin trafficking and function cease. 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. Soligenix intends to test VeloThrax™ at a 1,000 fold lower dose than previously tested for an intramuscular or intradermal vaccine.

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. VeloThrax™ will potentially be 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. This blend of proven yet innovative technologies will 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. Soligenix also proposes 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.

About 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™ (an oral immediate and delayed release formulation of the topically active corticosteroid BDP) is being developed for the treatment of GI ARS. Corticosteroids are the best understood and most 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. This is the same type of toxicity that occurs in Soligenix’s acute radiation enteritis clinical program with SGX201. As a result, there is a dual avenue of development for Soligenix, and OrbeShield™ is potentially a “dual use” compound, a desirable characteristic which is a specific priority of BARDA for ARS and other medical countermeasure indications. 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 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 for a total of three years and up to $6.4 million.

The FDA has cleared the IND application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS. 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 awarded 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 contract(s) could reach as much as $450 million.

About 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 >2 Gy 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 in 5-15 days. The GI tract is highly sensitive due to the requirement for incessant proliferation of 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 high-dose radiation. 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. Therefore, there is an urgent need to develop specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

SGX943/SGX101– for Treating Melioidosis

SGX943 is the research name for the finished drug product, containing the active ingredient SGX94, which is being studied in melioidosis. A preliminary study with SGX943 has demonstrated efficacy. Further preclinical studies are planned with the pursuit of grant funding. Because SGX943 directly targets the innate immune system (and does not attempt to kill the bacteria directly), 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. Thus, SGX943 may represent a much-needed novel and additive therapy for melioidosis. In February 2014, we were awarded a one-year NIAID SBIR grant of approximately $300,000 to further evaluate SGX943 as a treatment for melioidosis.

SGX101 is the research name for the human monoclonal antibody therapy for the treatment of melioidosis based upon Intrexon's advanced human antibody discovery, isolation, and production technologies. As this research and development program progresses, grant funding will be pursued.

About Melioidosis

Melioidosis is a potentially fatal infection caused by the Gram-negative bacillus, Burkholderia pseudomallei ("Bp"). Highly resistant to many antibiotics, Bp can cause an acute disease characterized by a fulminant pneumonia and a chronic condition that can recrudesce. There is no preventive vaccine or effective immunotherapy for melioidosis. Therefore, there is a significant 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. Moreover, the organism has a worldwide distribution and the full extent of global spread is likely underestimated. In Northeast Thailand, which has the highest incidence of melioidosis recorded in the world, 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. Melioidosis has been under recognized and is likely to be under-reported in China.

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 and rights for our current products in both the domestic and international markets. We believe that patent rights are one of our most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our products at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents designed to protect, preserve, 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, 2014. 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. We recognize 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 offering were accounted for as derivatives.

Revenue Recognition

Our revenues are primarily generated from government contracts and grants. Recording of revenue is applied in accordance with FASB ASC 605, Revenue Recognition, ASC 605-25 and/or Accounting Standard Update, ASU, 2009-13, Revenue Recognition – Multiple Element Arrangements. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the 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.

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

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. We evaluated the warrants' provisions and determined that warrants issued in connection with our June 2013 registered public offering contain provisions that protect holders from a decline in the issue price of our common stock (or "down-round" provisions) and contain net settlement provisions. Consequently, these warrants are recognized as liabilities at their fair value on the date of grant and remeasured to 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 2014 and 2013.

Stock-Based Compensation

From time to time, we issue common stock to vendors and consultants as compensation for services performed. These shares are typically issued as restricted stock, unless issued to non-affiliates under the 2005 Equity Incentive Plan, where the stock may be issued as unrestricted. The restricted stock can only have the restrictive legend removed if the shares underlying the certificate are sold pursuant to an effective registration statement, which we must file and have approved by the U.S. Securities and Exchange Commission if the shares underlying the certificate are sold pursuant to Rule 144, provided certain conditions are satisfied, or if the shares are sold pursuant to another exemption from the registration requirements of the Securities Act of 1933, as amended.

We determine stock-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. Stock-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, 2014 Compared to March 31, 2013

For the three months ended March 31, 2014, we had a net loss of $3,331,708 as compared to a net loss of $1,087,414 for same period in the prior year, representing an increase in the net loss of $2,244,294 or 206%. Included in the net loss for March 31, 2014 is a non-cash charge of $1,742,090 which represents the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering.

For the three months ended March 31, 2014, revenues relate to government contracts and grants awarded in support of our development in OrbeShield™ for the treatment of GI ARS, ThermoVax™, our vaccine heat stabilization technology,

and orBec® for the treatment of chronic GI GVHD. We had revenues of $910,597 as compared to $900,354 for the same period in the prior year, representing an increase of $10,243, or 1%. The increase in revenues was a result of continued progress on our OrbeShield™ contracts offset by reductions in grant revenues.

We incurred costs related to those revenues for the three months ended March 31, 2014 and 2013 of $628,981 and $743,657, respectively, representing a decrease of $114,676, or 15%. These costs relate to allocated employee costs and payments due to subcontractors in connection with research performed pursuant to the contracts and grants.

Our gross profit for the three months ended March 31, 2014 was $281,616, as compared to $156,697 for the same period in 2013, representing an increase of $124,919, or 80%. This increase is due primarily to the OrbeShield™ contracts which provides a management fee and higher negotiated reimbursement for fixed overhead as compared to government grants.

Research and development spending increased by $273,968, or 36%, to $1,030,621 for the three months ended March 31, 2014 as compared to $756,653 for the same period in 2013. The increase is due to expenses related to our Phase 2 clinical trial with SGX942 for the treatment of oral mucositis in patients with head and neck cancer, increased headcount and non-cash expenses for stock based compensation from stock options issued to existing and newly hired employees.

General and administrative expenses increased by $352,963, or 72%, to $840,904 for the three months ended March 31, 2014, as compared to $487,941 for the same period in 2013. The increase is due to an increase in outside professional services, increased headcount and non-cash expenses for stock based compensation from stock options issued to existing and newly hired employees.

Other income (expense) for the three months ended March 31, 2014 was $(1,741,799) as compared to $483 for the same period in 2013. The increase in expense is primarily attributable to a non-cash charge of $1,742,090 which represents the change in the fair value of the warrant liability related to warrants issued in connection with our June 2013 registered public offering.

Financial Condition

Cash and Working Capital

As of March 31, 2014, we had cash and cash equivalents of $5,606,850 as compared to $5,856,242 as of December 31, 2013, representing a decrease of $249,392 or 4%. As of March 31, 2014, we had working capital of $4,800,878, which excludes a non-cash warrant liability of $9,521,312, as compared to working capital of $5,855,046 as of December 31, 2013, excluding a non cash warrant liability of $8,281,247, representing a decrease of $1,054,168, or 18%. This decrease is primarily related to expenditures to support the Phase 2 clinical trial of SGX942.

Based on the Company’s current rate of cash outflows, cash on hand, proceeds from government grant and contract 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 approximately $32.3 million in active contract and grant funding still available to support our associated research programs into 2014. We plan to submit additional 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.

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- We will pursue sale of Net Operating Losses ("NOLs") in the state of New Jersey pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $750,356 in proceeds from the sale of NJ NOL in 2013, we expect to participate in the program during 2014 and beyond;
- We have a $10.0 million equity facility, with Lincoln Park, through October 2016, of which approximately $9.8 million is available; and
- We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately $10.9 million before any grant reimbursements, of which $3.8 million relates to the BioTherapeutics business and $7.1 million relates to the Vaccines/BioDefense business. We anticipate contract and grant revenues in the next 12 months of approximately $6.8 million to offset research and development expenses, primarily for the development of OrbeShield™ for the treatment of GI ARS and our ThermoVax™ vaccine thermostabilization technology.

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

	2014	2013
Research & Development Expenses		
Oral BDP	$271,438	$275,066
RiVax™ and ThermoVax™ Vaccines	177,318	398,641
SGX 94	495,294	50,789
Other	86,571	32,157
Total	$1,030,621	$756,653
Reimbursed under Government Grants and Contracts		
Oral BDP	$460,139	$63,619
RiVax™ and thermostable vaccines	168,842	680,038
Total	$628,981	$743,657
Grand Total	$1,659,602	$1,500,310

Contractional Obligations

The Company has commitments of approximately $344,000 as of March 31, 2014 relating to several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization milestones will occur.

On April 27, 2013, we entered into an exclusive channel collaboration agreement with Intrexon (the "Channel Agreement") 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 up to $7 million, if and when achieved.

On February 7, 2012, we entered into a lease agreement through March 31, 2015 for our existing office space. The rent for the first 12 months is approximately $8,000 per month, or approximately $18.25 per square foot on an annualized basis. This rent increases to approximately $8,310 per month, or approximately $19.00 per square foot on an annualized basis, for the remaining 24 months.

In February 2007, the Company's Board of Directors authorized the issuance of the following shares to Dr. Schaber and Dr. Brey upon 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 its assets are transferred from us and/or our stockholders to a third party: 50,000 common shares to Dr. Schaber and 10,000 common shares to Dr. Brey. The employment agreement with Dr. Schaber has been amended to reflect this obligation.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment.

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, 2014	$ 44,000	$81,000	$125,000
2015	75,000	33,000	108,000
2016	75,000	9,000	84,000
2017	75,000	2,000	77,000
2018	75,000	-	75,000
Total	$ 344,000	$125,000	$469,000

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, 2013. 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 2, 2014, the Company issued 6,000 shares of common stock to a vendor as partial consideration for services performed. The per share closing price of the Company’s common stock on January 2, 2014 was $1.99.

On February 21, 2014, the Company issued 50,000 shares of common stock to a vendor for as partial consideration for services performed. The per share price closing price of the Company’s common stock on February 21, 2014 was $2.19.

On February 24, 2014, the Company issued 15,000 shares of common stock to a vendor for partial consideration for services performed. The per share closing proce of the Company’s common stock on February 24, 2014 was $2.14.

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.

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.

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 12, 2014	by:	/s/ Christopher J. Schaber Christopher J. Schaber, PhD President and Chief Executive Officer (Principal Executive Officer)
May 12, 2014	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.