SOLIGENIX, INC.
Form 10-Q
May 03, 2013

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, 2013

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	08540
(Address of principal executive offices)	(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 01, 2013, 12,231,492 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, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$2,612,021	$ 3,356,380
Grants receivable	656,852	339,308
Prepaid expenses	170,778	140,693
Total current assets	3,439,651	3,836,381
Office furniture and equipment, net	11,539	12,995
Intangible assets, net	800,685	855,728
Total assets	$4,251,875	$ 4,705,104
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$1,651,740	$ 1,124,503
Accrued compensation	24,063	29,495
Total current liabilities	1,675,803	1,153,998
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 250,000 shares authorized; none issued or outstanding		-
Common stock, $.001 par value; 50,000,000 shares authorized; 11,194,968 shares and 11,168,905 shares issued and outstanding in 2013 and 2012, respectively	11,195	11,169
Additional paid-in capital	125,932,672	125,820,318
Accumulated deficit	(123,367,795)	(122,280,381)
Total shareholders' equity	2,576,072	3,551,106
Total liabilities and shareholders' equity	$4,251,875	$ 4,705,104

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, 2013 and 2012
(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Grant Revenue	$900,354	$647,418
Cost of revenues	(743,657)	(556,571)
Gross profit	156,697	90,847
Operating expenses:		
Research and development	756,653	876,794
General and administrative	487,941	655,043
Total operating expenses	1,244,594	1,531,837
Loss from operations	(1,087,897)	(1,440,990)
Other income:		
Interest income	483	2,235
Net loss	(1,087,414)	(1,438,755)
Basic and diluted net loss per share	$(0.10)	$(0.13)
Basic and diluted weighted average common shares outstanding	11,180,739	11,119,269

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Changes in Shareholders' Equity
For the Three Months Ended March 31, 2013
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2012	11,168,905	$11,169	$125,820,318	$(122,280,381)	$3,551,106
Issuance of restricted common stock to vendors	26,063	26	32,862	-	32,888
Stock-based compensation expense	-	-	79,492	-	79,492
Net loss	-	-	-	(1,087,414)	(1,087,414)
Balance, March 31, 2013	11,194,968	$11,195	$125,932,672	$(123,367,795)	$2,576,072

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)

	2013	2012
Operating activities:		
Net loss	$(1,087,414)	$(1,438,755)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	56,498	57,344
Restricted stock issued to employee	-	10,000
Restricted stock issued to vendors	32,888	-
Stock-based compensation	79,492	117,614
Change in operating assets and liabilities:		
Grants receivable	(317,544)	38,068
Taxes receivable	-	574,157
Prepaid expenses	(30,085)	51,726
Accounts payable	527,238	(72,999)
Accrued compensation	(5,432)	(12,690)
Total adjustments	343,055	763,220
Net cash used in operating activities	(744,359)	(675,535)
Net decrease in cash and cash equivalents	(744,359)	(675,535)
Cash and cash equivalents at beginning of period	3,356,380	5,996,668
Cash and cash equivalents at end of period	$2,612,021	$5,321,133

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," "we" or "us") is a clinical stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense. Soligenix'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 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, and VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome ("GI ARS") therapeutic. The advanced development of these vaccine programs is currently supported by the Company's heat stabilization technology, known as ThermoVax™, under existing and on-going grant funding.

The Company generates revenues under four active grants primarily from the National Institutes of Health ("NIH").

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 FDA regulations, litigation, and product liability. Results for the quarter ended March 31, 2013 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of March 31, 2013, the Company had cash and cash equivalents of $2,612,021 as compared to $3,356,380 as of December 31, 2012, representing a decrease of $744,359 or 22%. As of March 31, 2013, the Company had working capital of $1,763,848 as compared to working capital of $2,682,383 as of December 31, 2012, representing a decrease of $918,535 or 34%. The decrease in cash and working capital was primarely due to cash used in operating activities. For the three months ended March 31, 2013, the Company's cash used in operating activities was $744,359 as compared to $675,535 for the same period in 2012, representing an increase of $68,824, or 10%.

Management's business strategy can be outlined as follows:

Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203, for the treatment of pediatric Crohn's disease;

Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;

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 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;

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Continue to apply for and secure additional government funding for each of our BioTherapeutics and Bio/Defense programs through grants, contracts and/or procurements; and

Explore other business development and acquisition strategies.

Based on the Company's current rate of cash outflows, cash on hand and proceeds from its grant programs, 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 into the second quarter of 2014.

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

We have instituted a cost reduction plan which has reduced headcount, and we will continue to reduce costs wherever possible.

The Company has approximately $3.6 million in active grant funding still available to support its associated research programs through 2014 and beyond. The Company plans to submit additional grant applications for further support of its programs with various funding agencies.

The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.

The Company will pursue 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 $521,458 in proceeds pursuant to NOL sales in 2012, the Company expects to participate in the program during 2013 and beyond; 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 Receivable

Grants receivable consist of unbilled amounts due from various grants from the NIH for costs incurred under reimbursement contracts prior to the period end under reimbursement contracts. The amounts were billed to the NIH 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 incur any capitalizable patent related costs during the quarters ended March 31, 2013 and 2012.

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, 2013 and 2012.

Fair Value of Financial Instruments

Accounting principles generally accepted in the U.S. require that fair values be disclosed for the Company's financial instruments. The carrying amounts of the Company's financial instruments, which include grants receivable and current liabilities, are considered to be representative of their respective fair values.

Revenue Recognition

Principally the Company's revenues are generated from NIH grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). 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 the Company incurs 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.

Stock-Based Compensation

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 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.

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 Company did not issue any options during the quarters ending March 31, 2013 and 2012.

The fair value of options to be granted are 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, 2013 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 2013 and 2012. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a

liability for uncertain tax positions at March 31, 2013 and 2012. 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.

	Three Months Ended March 31,					
	2013			2012		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	(1,087,414)	11,180,739	$(0.10)	(1,438,755)	11,119,269	$(0.13)

Shares issuable upon the exercise of options and warrants outstanding at March 31, 2013 and 2012 were 1,454,755 and 1,496,898 and 2,843,338 and 2,576,341 shares, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2013 was $3.20 and $3.13 per share, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2012 was $3.72 and $4.32 per share, respectively. No options or warrants were included in the 2013 and 2012 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

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, 2013				
Licenses	7.5	$ 462,234	$ 258,737	$ 203,497
Patents	3.2	1,893,185	1,295,997	597,188
Total	4.0	$ 2,355,419	$ 1,554,734	$ 800,685
December 31, 2012				
Licenses	7.7	$ 462,234	$ 252,019	$ 210,215
Patents	3.3	1,893,185	1,247,672	645,513
Total	4.2	$ 2,355,419	$ 1,499,691	$ 855,728

Amortization expense was $55,043 and $55,654 for the three months ended March 31, 2013 and 2012, respectively.

Based on the balance of licenses and patents at March 31, 2013, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
2013	$ 222,800
2014	$ 222,800
2015	$ 133,000
2016	$ 61,800
2017	$ 20,800

License fees and royalty payments are expensed annually as incurred as the Company does not attribute any future benefits other than within that period.

Note 4. Income Taxes

The Company had NOLs at December 31, 2012 of approximately $79,463,000 for federal tax purposes and approximately $9,498,000 of New Jersey NOL carry forwards remaining after the sale of unused NOL carry forwards, portions of which are currently expiring each year until 2031. In addition, the Company had $3,068,000 of various tax credits that started expiring in December 2012 and will continue to expire through December 2030. 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 2010 for Federal and 2009 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, 2013 and 2012 due to losses and full valuation allowances against net deferred tax assets.

Note 5. Shareholders' Equity

Preferred Stock

The Company has 250,000 shares of preferred stock authorized, none of which are issued or outstanding.

Common Stock

During the three months ended March 31, 2013, the Company issued 26,063 shares of common stock to vendors as partial consideration for services performed.

Note 6. Commitments and Contingencies

The Company has commitments of approximately $368,800 as of March 31, 2013 for 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 success will occur.

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. The Company recognized an expense of $95,625 during the quarter ended March 31, 2012 related to severance and healthcare benefits paid to the prior Chief Financial Officer of the Company.

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
2013	$ 43,800	$ 79,100	$ 122,900
2014	100,000	101,200	201,200
2015	75,000	25,000	100,000
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	$ 368,800	$ 205,300	$ 574,100

Note 7. 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,	
	2013	2012
Grant Revenue		
Vaccines/BioDefense	$829,849	$597,605
BioTherapeutics	70,505	49,813
Total	$900,354	$647,418
Loss from Operations		
Vaccines/BioDefense	$(30,995)	$(128,366)
BioTherapeutics	(457,625)	(726,042)
Corporate	(599,277)	(586,582)
Total	$(1,087,897)	$(1,440,990)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$27,667	$27,997
BioTherapeutics	28,395	28,840
Corporate	436	507
Total	$56,498	$57,344
Interest Income		
Corporate	$483	$2,235
Stock-Based Compensation		
Vaccines/BioDefense	$11,121	$2,130
BioTherapeutics	21,036	56,240
Corporate	47,335	59,064
Total	$79,492	$117,614

	As of March 31, 2013	As of December 31, 2012
Identifiable Assets		
Vaccines/BioDefense	$936,695	$628,494
BioTherapeutics	519,391	566,111
Corporate	2,795,789	3,510,499
Total	$4,251,875	$4,705,104

Note 8. Subsequent Event

On April 27, 2013, the Company entered into a Stock Issuance Agreement with Intrexon Corporation (“Intrexon”), pursuant to which the Company has issued to Intrexon 1,034,483 shares of Common Stock in consideration for the execution and delivery of an Exclusive Channel Agreement (the “Channel Agreement”). The shares issued to Intrexon represent approximately 8.5% of the issued and outstanding shares of Common Stock as of the date of this report.

The Channel Agreement with Intrexon enables the Company to use Intrexon’s advanced human antibody discovery, isolation, and production technologies for the development and commercialization of human monoclonal antibody therapies for a new biodefense and infectious disease application.

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, 2012. 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:

Business Overview

We are a clinical stage biopharmaceutical company that is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. 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, and OrbeShield™, our gastrointestinal acute radiation syndrome ("GI ARS") 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.

An outline for our business strategy follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn's disease;
- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- 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 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;

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Continue to apply for and secure additional government funding for each of our BioTherapeutics and Bio/Defense programs through grants, contracts and/or procurements; and

Explore other business development and acquisition strategies.

We were incorporated in Delaware in 1987. 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	IND clearance and Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical trial planned for the first half of 2013, with data expected in the first half of 2013; Phase 2/3 clinical trial planned for the second half of 2013, with data expected in the second half of 2014
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated Phase 2 trial planned for the first half of 2014, with data expected in the first half of 2015
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned for 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 2014
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2014
OrbeShield™	Therapeutic against GI ARS	Follow-on pre-clinical study initiated; Initial pre-clinical study complete; protection observed in canine

BioTherapeutics Overview

SGX94

In December 2012, we acquired a novel 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 University of British Columbia, 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.

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

SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is poised to start a Phase 2 clinical study in oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we plan to request orphan drug and/or Fast Track designations from the FDA in the first half of 2013.

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 published studies and reports, that Mucositis affects approximately 500,000 people in the United States ("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 published studies and reports, 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 ("HCT"), 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.

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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 for the treatment of pediatric Crohn's disease as well as Fast Track designation. 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 SGX203 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.

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 published studies and reports, 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 Small Business Innovation and Research ("SBIR") grant awarded by the National Institutes of Health ("NIH"). We are currently working with our Radiation Enteritis medical advisory board to determine potential next steps forward with the clinical development program.

We have received Fast Track designation from the FDA for SGX201 for 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 B12 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 published studies and reports, 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 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 NIH 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 published studies and reports, 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

Soligenix's 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. The World Health Organization ("WHO") reported that 50% of all vaccines around the world are wasted which includes thermostability issues. 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 National Institute of Allergy and Infectious Diseases ("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 Soligenix's 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 for six months, all of the animals vaccinated with the lyophilized RiVax™ vaccine

developed potent and high titer neutralizing antibodies. Confirmatory results have extended the stability to six months 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 Soligenix 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 application number 12/532,225 filed January 29, 2010 entitled “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 entitled “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 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 entitled "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 entitled “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.

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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 entitled 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)

The Centers for Disease Control (“CDC”) 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. 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 (“CBMS-JVAP”) of the Department of Defense (“DoD”). This RFI was entitled “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 Soligenix’s 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™, Soligenix believes that it 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, 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 contracts 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 2 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 Biomedical Advanced Research and Development Authority (BARDA) for ARS and other medical countermeasure indications.

BARDA recently invited Soligenix to submit a full contract proposal for a potential multi-year, multi-million dollar contract to develop OrbeShield™ from its current level of technical readiness to potential FDA approval. In response, Soligenix submitted its contract proposal in February 2013. We expect a response in the second half of 2013.

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.

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 TBI. Although the hematopoietic syndrome can be rescued by bone marrow transplantation or growth factor administration, there is no established treatment or preventive measure for the GI damage that occurs after high-dose radiation. Therefore, there is an urgent need to develop specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

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.

Research and Development Costs

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

Revenue Recognition

Principally our revenues are generated from NIH grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). 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.

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, 2013 Compared to March 31, 2012

For the three months ended March 31, 2013, we had a net loss of $1,087,414 as compared to a net loss of $1,438,755 for same period in the prior year, representing a reduction in the net loss of $351,341 or 24%.

For the three months ended March 31, 2013, revenues and associated costs relate to NIH grants awarded in support of our development of ricin and thermostable vaccines and oral BDP. For the three months ended March 31, 2013, we had revenues of $900,354 as compared to $647,418 for the same period in the prior year, representing an increase of $252,936, or 39%. The increases in revenues were a result of increases in NIH grant revenues and the development work underlying them.

We incurred costs related to those revenues for the three months ended March 31, 2013 and 2012 of $743,657 and $556,571, respectively, representing an increase of $187,086, or 34%. These costs relate to allocated employee costs and payments made to subcontractors in connection with research performed pursuant to the grants.

Our gross profit for the three months ended March 31, 2012 was $156,697, as compared to $90,847 for the same period in 2012, representing an increase of $65,850, or 72%. The increase in gross profit follows directly from the increases in grant revenues discussed above.

Research and development spending decreased by $120,141, or 14%, to $756,653 for the three months ended March 31, 2013 as compared to $876,794 for the same period in 2012. The decrease is due to a reduction in headcount and additional allocation of employee costs pursuant to grant awards.

General and administrative expenses decreased by $167,102, or 26%, to $487,941 for the three months ended March 31, 2013, as compared to $655,043 for the same period in 2012. The decrease is due to a reduction in headcount and outside professional services.

Financial Condition

Cash and Working Capital

As of March 31, 2013, we had cash and cash equivalents of $2,612,021 as compared to $3,356,380 as of December 31, 2012, representing a decrease of $744,359 or 22%. As of March 31, 2013, we had working capital of $1,763,848 as compared to working capital of $2,682,383 as of December 31, 2012, representing a decrease of $918,535, or 34%.

Based on our current rate of cash outflows, cash on hand, the timely collection of milestone payments under collaboration agreements, proceeds from our grant-funded programs, reductions in headcount and expected proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, we believe that our current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the second quarter of 2014.

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

- We have instituted a cost reduction plan which has reduced headcount, and we will continue to reduce costs wherever possible.
- We have approximately $3.6 million in active 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.
- 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 $521,458 in proceeds from the sale of NJ NOL in 2012, we expect to participate in this expanded program during 2013 and beyond as the program 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 $3.4 million before any grant reimbursements, of which $0.6 million relates to the BioTherapeutics business and $2.8 million relates to the Vaccines/BioDefense business. We anticipate grant revenues in the next 12 months of approximately $3.1 million to offset research and development expenses, primarily for the development of our ThermoVax™ vaccine technology.

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

	2013	2012
Research & Development Expenses		
Oral BDP	$275,066	$360,070
RiVax™ and ThermoVax™ Vaccines	398,641	458,174
SGX 94	50,789	-
Other	32,157	58,550
Total	$756,653	$876,794
Reimbursed under NIH Grants		
Oral BDP	$63,619	$49,813
RiVax™ and thermostable vaccines	680,038	506,758
Total	$743,657	$556,571
Grand Total	$1,500,310	$1,433,365

Contractional Obligations

The Company has commitments of approximately $368,800 as of March 31, 2013 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 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. On February 15, 2012, our employment agreement with our former Chief Financial Officer was terminated.

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
2013	$ 43,800	$ 79,100	$ 122,900
2014	100,000	101,200	201,200
2015	75,000	25,000	100,000
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	$ 368,800	$ 205,300	$ 574,100

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4 - CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

Changes in Internal Controls

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

PART II – OTHER INFORMATION.

ITEM 1A – RISK FACTORS

We have identified no additional risk factors other than those included in Part I, Item 1A of our Form 10-K for the fiscal year ended December 31, 2012. 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 10, 2013, the Company issued 11,063 shares of common stock to a consultant as partial consideration for services performed. The per share closing price of the Company’s common stock on December 30, 2012 was $0.60. The issuance of these shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

On March 13, 2013, the Company issued 15,000 shares of common stock to a vender for as partial consideration for services performed. The per share price closing price of the Company’s common stock on March 13, 2013 was $1.75. The issuance of these shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

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 03, 2013	by /s/ Christopher J. Schaber Christopher J. Schaber, PhD President and Chief Executive Officer (Principal Executive Officer)
May 03, 2013	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.