SOLIGENIX, INC.
Form 10-Q
May 14, 2012

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, 2012

or

( ) TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File No. 000-16929

SOLIGENIX, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	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 (Check one).

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 10, 2012, 11,122,199 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
(Unaudited)

	March 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 5,321,133	$ 5,996,668
Grants receivable	324,404	362,473
Taxes receivable	-	574,157
Prepaid expenses	144,037	195,762
Total current assets	5,789,574	7,129,060
Office furniture and equipment, net	13,342	15,032
Intangible assets, net	1,023,912	1,079,566
Total assets	$ 6,826,828	$ 8,223,658
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,230,556	$ 1,303,555
Accrued compensation	116,371	129,061
Total current liabilities	1,346,927	1,432,616
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 250,000 shares authorized; none issued or outstanding	-	-
Common stock, $.001 par value; 20,000,000 shares authorized; 11,122,199 shares and 11,105,532 shares issued and outstanding in 2012 and 2011, respectively	11,123	11,106
Additional paid-in capital	125,024,906	124,897,309
Accumulated deficit	(119,556,128)	(118,117,373)
Total shareholders' equity	5,479,901	6,791,042
Total liabilities and shareholders' equity	$ 6,826,828	$ 8,223,658

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, 2012 and 2011
(Unaudited)

	Three Months Ended March 31,	
	2012	2011
Revenues, from grants	$ 647,418	$ 808,005
Cost of revenues	(556,571)	(554,037)
Gross profit	90,847	253,968
Operating expenses:		
Research and development	876,794	1,372,804
General and administrative	655,043	604,010
Total operating expenses	1,531,837	1,976,814
Loss from operations	(1,440,990)	(1,722,846)
Other income:		
Interest income	2,235	2,435
Net loss	(1,438,755)	(1,720,411)
Basic and diluted net loss per share	$ (0.13)	$ (0.16)
Basic and diluted weighted average common shares outstanding	11,119,269	10,842,277

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, 2012
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2011	11,105,532	$11,106	$124,897,309	$(118,117,373)	$6,791,042
Issuance of restricted common stock to employee	16,667	17	9,983	-	10,000
Stock-based compensation expense	-	-	117,614	-	117,614
Net loss	-	-	-	(1,438,755)	(1,438,755)
Balance, March 31, 2012	11,122,199	$11,123	$125,024,906	$(119,556,128)	$5,479,901

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)

	2012	2011
Operating activities:		
Net loss	$ (1,438,755)	$ (1,720,411)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	57,344	51,427
Restricted stock issued to employee	10,000	2,686
Stock-based compensation	117,614	156,767
Change in operating assets and liabilities:		
Grants receivable	38,068	(48,139)
Taxes receivable	574,157	247,542
Prepaid expenses	51,726	92,772
Accounts payable	(72,999)	(255,879
Accrued compensation	(12,690)	(202,312)
Total adjustments	763,220	44,864
Net cash used in operating activities	(675,535)	(1,675,547)
Investing activities:		
Acquisition of intangible assets	-	(26,656)
Net cash used in investing activities	-	(26,656)
Financing activities:		
Proceeds from sale of common stock pursuant to equity line	-	130,000
Proceeds from exercise of options and warrants	-	68,750
Net cash provided by financing activities		198,750
Net decrease in cash and cash equivalents	(675,535)	(1,503,453)
Cash and cash equivalents at beginning of period	5,996,668	7,451,714
Cash and cash equivalents at end of period	$ 5,321,133	$ 5,948,261

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 development-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. Soligenix's BioTherapeutics business segment intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, while the Company's collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") will commercialize orBec® and oral BDP in North America and Europe, if approved. On September 15, 2011, the Company's confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD") was stopped at the recommendation of an independent Data Safety Monitoring Board ("DSMB"). Preliminary findings indicate that there are no significant differences between the orBec® group and placebo group for the primary endpoint, as well as for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, the Company will be terminating the development of orBec® for the treatment of acute GI GVHD.

Additionally, the Company is actively developing oral BDP in other therapeutic indications, such as pediatric Crohn's disease and acute radiation enteritis. Soligenix's Vaccines/BioDefense business segment includes active development programs for RiVax™, its ricin toxin vaccine, and VeloThrax™, its anthrax vaccine, and OrbeShield™, its gastrointestinal acute radiation syndrome ("GI ARS") therapeutic. The advanced development of the vaccine programs will be supported by the heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding.

The Company generates revenues primarily from the National Institutes of Health (the "NIH") under two active grants, license fees and from its license milestones once achieved from Sigma-Tau.

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.

Liquidity

As of March 31, 2012, the Company had cash and cash equivalents of $5,321,133 as compared to $5,996,668 as of December 31, 2011, representing a decrease of $675,535 or 11%. As of March 31, 2012, the Company had working capital of $4,442,647 as compared to working capital of $5,696,444 as of December 31, 2011, representing a decrease of $1,253,797 or 22%. The decrease in cash and working capital was the result of the cash used in operating activities. For the three months ended March 31, 2012, the Company's cash used in operating activities was $675,535 as compared to $1,675,547 for the same period in 2011, representing a decrease of $1,000,012, or 60%. The decrease is primarily related to the termination of the Company's pivotal phase 3 trial, orBec®, for the treatment of acute GI GVHD.

Management's business plan can be outlined as follows:

- Initiate a Phase 2A clinical trial of orBec® in pediatric Crohn's disease;
- Use RiVax™ and VeloThrax™ to support development efforts with its proprietary vaccine heat stabilization technology, 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;
- Apply for and secure further government funding for development of its BioDefense programs, namely RiVax™, VeloThrax™, and OrbeShield™ in GI ARS;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute radiation enteritis, prevention of acute GVHD, and treatment of chronic GI GVHD;
- Continue to secure additional government funding for each of its 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 acquisition strategies.

Based on the Company's current rate of cash outflows, cash on hand, , proceeds from its grant-funded programs, reductions in headcount and expected 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 2013.

The Company's plans with respect to its liquidity management include the following:

- The Company has instituted a cost reduction plan which has reduced headcount and will continue to reduce costs wherever possible.
- The Company has approximately $3.8 million in active grant funding still available to support its associated research programs into 2014. 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 $574,157 in proceeds pursuant to NOL sales in 2011, the Company expects to participate in the expanded program during 2012 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.

Reverse Stock Split

On February 1, 2012, the Company completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1-for-20, whereby, once effective, every 20 shares of its common stock was exchanged for one share of its common stock. Its common stock began trading on the OTCBB on a reverse split basis at the market opening on February 2, 2012. All share and per share data have been restated to reflect this reverse stock split.

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 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. The Company considers the grants receivable to be fully collectible. 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 capitalized patent related costs during the quarter ended March 31, 2012; the Company capitalized $26,656 in patent related costs during the quarter ended March 31, 2011.

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.

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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 all of 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 option's price is re-measured using the Black-Scholes model at the end of each three month reporting period.

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The fair value of options in accordance with FASB ASC 718, Stock Compensation, was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions:

- a dividend yield of 0%;
- an expected life of 4 years;
- volatility of 123% for 2011
- forfeitures at a rate of 12%; and
- risk-free interest rate of 1.47% in 2011.

The Company did not issue any options for the quarter ending March 31, 2012.

The Company estimates these values based on the assumptions that have been historically available. The fair value of each options 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, 2012 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 2012 and 2011. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at March 31, 2012 and 2011. The income tax returns for 2008, 2009 and 2010 are subject to examination by the IRS and other various taxing authorities, generally for three years after they were filed.

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 as adjusted for the 1-for-20 reverse stock split effective February 1, 2012. 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 or warrants were included in the 2012 and 2011 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses or options and warrants for which the strike price exceeds the quoted market value at period end.

	Three Months Ended March 31,					
	2012			2011		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	(1,438,755)	11,119,269	$(0.13)	$(1,720,411)	10,842,277	$(0.16)

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Shares issuable upon the exercise of options and warrants outstanding at March 31, 2012 and 2011 were 1,496,898 and 1,331,802 and 2,576,341 and 2,704,569 shares, 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. The weighted average exercise price of the Company's stock options and warrants outstanding at March 31, 2011 was $4.80 and $4.40 per share, respectively. No options or warrants were included in the 2012 and 2011 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 Amortization Period (years)	Cost	Accumulated Amortization	Net Book Value
March 31, 2012				
Licenses	8.47	462,234	231,499	230,735
Patents	3.2	1,893,185	1,100,008	793,177
Total	4.2	2,355,419	1,331,507	1,023,912
December 31, 2011				
Licenses	8.72	$ 462,234	$ 224,708	$ 237,526
Patents	3.3	1,893,185	1,051,145	842,040
Total	4.4	$ 2,355,419	$ 1,275,853	$ 1,079,566

Amortization expense was $55,654 and $49,637 for the three months ended March 31, 2012 and 2011, respectively.

Based on the balance of licenses and patents at March 31, 2012, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
2012	$ 222,800
2013	$ 222,800
2014	$ 222,800
2015	$ 222,800
2016	$ 132,700

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

At March 31, 2012, the Company had NOLs of approximately $76,000,000 for federal tax purposes and approximately $19,000,000 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 $3,462,000 of various tax credits that started expiring in December 2011 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 likely that the utilization of the NOLs may be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to Federal income tax assessment for years before 2008 and 2007 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 by the Internal Revenue Service and state authorities for purposes of determining the amount of net operating loss carryforward that can be used to reduce taxable income.

The Company has no tax provision for the three month periods ended March 31, 2012 and 2011 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

The following items represent transactions in the Company's common stock for the three months ended March 31, 2012:

The Company issued 16,667 shares of restricted common stock to an employee as part of the 2011 annual bonus paid in January 2012. An expense of $10,000 was reflected in the Company's financial statements for the period ended December, 31, 2011.

Note 6. Commitments and Contingencies

The Company has commitments of approximately $405,000 as of March 31, 2012 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 success will occur.

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On April 1, 2009, the Company entered into a sub-lease agreement through March 31, 2012 for office space in Princeton, New Jersey. The Company was required to provide 4 months of rent as a security deposit. The rent for the first 18 months was approximately $7,500 per month, or $17.00 per square foot. This rent increased to approximately $7,650 per month, or $17.50 per square foot, for the remaining 18 months. The Company records rent on a straight line basis. 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. On February 15, 2012, Mr. Myrianthopoulos' employment agreement was terminated. However, he continues to serve the Company as a member of the Board of Directors.

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	Severance	Total
2012	$ 105,000	$ 76,203	$ 110,425	$ 291,628
2013	75,000	104,559	-	179,559
2014	75,000	101,198	-	176,198
2015	75,000	24,938	-	99,938
2016	75,000	-	-	75,000
Total	$ 405,000	$ 306,898	$ 110,425	$ 822,323

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,	
	2012	2011
Revenues, Principally from Grants		
Vaccines/BioDefense	$ 597,605	$ 536,586
BioTherapeutics	49,813	271,419
Total	$ 647,418	$ 808,005
Income (Loss) from Operations		
Vaccines/BioDefense	$ (128,366)	$ 67,478
BioTherapeutics	(726,042)	(1,381,328)
Corporate	(586,582)	(408,996)
Total	$ (1,440,990)	$ (1,722,846)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$ 27,997	$ 9,689
BioTherapeutics	28,840	41,200
Corporate	507	538
Total	$ 57,344	$ 51,427
Interest Income, Net		
Corporate	$ 2,235	$ 2,435
Stock-Based Compensation		
Vaccines/BioDefense	$ 2,130	$ 18,416
BioTherapeutics	56,240	98,253
Corporate	59,064	40,098
Total	$ 117,614	$ 156,767
Identifiable Assets		
Vaccines/BioDefense	$ 641,729	$ 525,946
BioTherapeutics	706,399	886,602
Corporate	5,478,700	6,035,599
Total	$ 6,826,828	$ 7,448,147

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL 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 including Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2011. 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 expression, 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 SEC 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 SEC that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Overview:

Business Overview

Soligenix, Inc. was incorporated in Delaware in 1987. We are a development stage biopharmaceutical company focused on developing products to treat the life-threatening side effects of cancer treatment and serious gastrointestinal 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 intends to develop orBec® (oral beclomethasone dipropionate, or oral BDP) and other biotherapeutic products, while our collaboration partner, Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") will commercialize orBec® and oral BDP in North America and Europe if approved. On September 15, 2011 the Company's confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD") was stopped at the recommendation of an independent Data Safety Monitoring Board ("DSMB"). Preliminary findings indicate that there are no significant differences between the orBec® group and placebo group for the primary endpoint, as well as for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, we will be terminating the development of orBec® for the treatment of acute GI GVHD.

Additionally, we are actively developing oral BDP in other therapeutic indications, such as pediatric Crohn's disease and radiation enteritis. Our Vaccines/BioDefense business segment includes RiVax™, our ricin toxin vaccine, and VeloThraxTM, our anthrax vaccine, and OrbeShieldTM, our gastrointestinal acute radiation syndrome ("GI ARS") program. The advanced development of the vaccine programs will be supported by our heat stabilization technology under existing and ongoing government grant funding.

Our business plan can be outlined as follows:

- Initiate a Phase 2 clinical trial of oral BDP known as SGX203 in pediatric Crohn's disease;
- Use RiVax™ and VeloThrax™ to support development efforts 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;
- Apply for and secure further government funding for development of our BioDefense programs, namely RiVax™, VeloThrax™, and OrbeShield™ in GI ARS;
- Evaluate the effectiveness of orBec®/Oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as prevention of acute radiation enteritis, prevention of acute GVHD, and treatment of chronic GI GVHD;
- Continue to secure additional government funding for each of our BioTherapeutics program through grants, contracts and/or procurements;
- Acquire or in-license new clinical-stage compounds for development; and
- Explore other business development and acquisition strategies.

Our principal 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
orBec®	Treatment of Acute GI GVHD	Pivotal Phase 3 trial terminated; Preliminary analysis complete
orBec®	Prevention of Acute GVHD	Phase 2 trial completed
orBec®	Treatment of Chronic GI GVHD	Potential Phase 2 trial under review
SGX201	Acute Radiation Enteritis	Phase 1/2 trial complete; safety and preliminary efficacy demonstrated
SGX203	Pediatric Crohn's disease	Phase 2 clinical program planned
LPM™ Leuprolide	Endometriosis and Prostate Cancer	Pre-clinical

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 enrollment complete; complete results expected in 2012
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical
OrbeShield™	Therapeutic against GI ARS	Initial pre-clinical study complete; successful protection of dogs

BioTherapeutics Overview

orBec® and Oral BDP

orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of acute GI GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs to treat acute GI GVHD. The active ingredient in orBec® is beclomethasone dipropionate ("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® 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 data from the prior Phase 3 study of orBec®, the recent confirmatory Phase 3 study was a highly powered, double-blind, randomized, placebo-controlled, multi-center trial that enrolled 140 patients. This trial has been supported in part by a $1.2 million FDA Orphan Products grant awarded to Soligenix. The primary endpoint is the treatment failure rate at Study Day 80. On September 15, 2011, the Company's confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD") was stopped at the recommendation of an independent Data Safety Monitoring Board ("DSMB"). Preliminary findings indicate that there are no significant differences between the orBec® group and placebo group for the primary endpoint, as well as for the pre-specified secondary endpoints. Given the outcome of the Phase 3 study, the Company will be terminating the development of orBec® for the treatment of acute GI GVHD.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, orBec® would benefit from orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD, as well as an orphan drug designation in the U.S for the treatment of chronic GI GVHD. Orphan drug designations provide for 7 and 10 years of market exclusivity upon approval in the U.S and Europe, respectively.

Commercialization and Market

On February 11, 2009, we entered into a collaboration and supply agreement with Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") for the commercialization of orBec®/Oral BDP. Sigma-Tau is a pharmaceutical company that develops novel therapies for the unmet needs of patients with rare diseases. Pursuant to this agreement, Sigma-Tau has an exclusive license to commercialize orBec®/Oral BDP in the U.S., Canada and Mexico (the "Territory"). Sigma-Tau is obligated to make payments upon the attainment of significant milestones, as set forth in the agreement. The first milestone payment of $1 million was made in connection with the enrollment of the first patient in our confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD in September 2009. Total additional milestone payments due from Sigma-Tau for orBec® under the agreement could reach up to $9 million. Sigma-Tau will pay us a 35% royalty (Soligenix to provide finished drug product) on net sales in the Territory as well as pay for commercialization expenses, including launch activities. In connection with the execution of the collaboration and supply agreement, we entered into a common stock purchase agreement with Sigma-Tau pursuant to which we sold 25 million shares of our common stock to Sigma-Tau for $0.18 per share, for an aggregate price of $4,500,000. The purchase price was equal to one hundred fifty percent (150%) of the average trading price of our common stock over the five trading days prior to February 11, 2009.

The Collaboration and Supply Agreement dated February 11, 2009 between us and Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau") expires on a country-by-country basis on the later of: (i) 10 years after the date of the first commercial sale of oral beclomethasone dipropionate ("orBec®") by Sigma-Tau in such country; or (ii) the expiration of the last to expire of the Company's patents and patent applications relating to orBec® in such country. Upon the expiration of the initial term, on a country-by-country basis, the agreement is automatically renewed for periods of five years. During such renewal periods, we and Sigma-Tau have the right to terminate the agreement for convenience upon six months and 18 months, respectively, prior written notice. If we terminates the agreement for convenience, we are required to transfer to Sigma-Tau or its designee, for no consideration, the U.S. Food and Drug Administration (the "FDA") and European Medicines Agency ("EMEA") authorizations which are necessary for the marketing, use, distribution and sale of orBec® and all relevant data and know-how necessary to manufacture and commercialize orBec® in the country and grant to Sigma-Tau a royalty-free, fully paid, perpetual and irrevocable license, with the right to sublicense, to the trademark "orBec" and such know-how.

Either party may terminate the agreement: (i) in the event the other party breaches any material obligation; or (ii) upon the initiation of a proceeding in bankruptcy (voluntary or involuntary), reorganization, dissolution, liquidation or similar proceeding or occurrence. We also have the right to terminate the agreement in the event that Sigma-Tau challenges or assists any third party in the challenge of the validity of any of our patents or patent applications relating to orBec®.

Upon termination other than for breach by Sigma-Tau, Sigma-Tau has the right to process and sell its inventory for a period of three months following the date of termination, subject to the payment of the amounts owed under the agreement, to us and continued compliance with the terms of the agreement.

On July 28, 2011, we announced the expansion and amendment of our North American licensing partnership with Sigma-Tau for the development and commercialization of orBec®/oral BDP into the "European Territory", as defined in the amendment. Pursuant to this amendment, we received an up-front non-refundable payment of $5 million and granted Sigma-Tau an exclusive license to commercialize orBec®/oral BDP in the European territory. The amendment requires Sigma-Tau to make additional payments to us in the aggregate amount of $11 million upon the achievement of certain milestones. The amendment also requires Sigma-Tau to pay us a 40% royalty (Soligenix to provide finished drug product) on net sales in the European Territory and pay for all commercialization expenses, including launch activities.

We believe the potential worldwide market for orBec®/Oral BDP is in excess of $500 million for all GI applications, namely, Crohn's disease, radiation enteritis, GI ARS, and all GVHD applications.

About GVHD

GVHD occurs in patients following allogeneic stem cell transplantation in which tissues of the host, most frequently the gut, liver, and skin, are attacked by lymphocytes from the donor (graft) marrow. Patients with mild to moderate GI GVHD present to the clinic with early satiety, anorexia, nausea, vomiting and diarrhea. If left untreated, symptoms of GI GVHD persist and can progress to necrosis and exfoliation of most of the epithelial cells of the intestinal mucosa, frequently a fatal condition. Approximately 50% of the more than 10,000 annual allogeneic transplantation patients in the U.S. will develop some form of acute GI GVHD.

GI GVHD is one of the most common causes for the failure of stem cell transplantation. These procedures are being increasingly utilized to treat leukemia and other cancer patients with the prospect of eliminating residual disease and reducing the likelihood of relapse. Although systemic immunosuppressives are currently used to control GI GVHD, they substantially inhibit the highly desirable Graft-versus-Leukemia ("GVL") effect of stem cell transplantations, leading to high rates of aggressive forms of relapse, as well as substantial rates of mortality due to opportunistic infection.

About Allogeneic Hematopoietic Cell Transplantation

Allogeneic hematopoietic cell transplantation ("HCT") is considered a potentially curative option for many leukemias as well as other forms of blood cancer. In an allogeneic HCT procedure, hematopoietic stem cells are harvested from the blood or bone marrow of a closely matched relative or unrelated person, and are transplanted into the patient following either high-dose chemotherapy or intense immunosuppressive conditioning therapy. The curative potential of allogeneic HCT is now partly attributed to the GVL or Graft-versus-Tumor effects of the newly transplanted donor cells to recognize and destroy malignant cells in the recipient patient.

The use of allogeneic HCT has grown substantially over the last decade due to advances in human immunogenetics, the establishment of unrelated donor programs, the use of cord blood as a source of hematopoietic stem cells and the advent of non-myeloablative conditioning regimens, or mini-transplants, that avoid the side effects of high-dose chemotherapy. Based on the latest statistics available, it is estimated that there are more than 10,000 allogeneic HCT procedures annually in the U.S. and a comparable number in Europe. Estimates as to the current annual rate of increase in these procedures are as high as 20%. High rates of morbidity and mortality occur in this patient population. Clinical trials are also underway testing allogeneic HCT for treatment of some metastatic solid tumors such as breast cancer, renal cell carcinoma, melanoma and ovarian cancer. Allogeneic transplantation has also been studied as a curative therapy for several genetic disorders, including immunodeficiency syndromes, inborn errors of metabolism, and sickle cell disease. The primary toxicity of allogeneic HCT, however, is GVHD in which the newly transplanted donor cells damage cells in the recipient's gastrointestinal tract, liver and skin.

Future Potential Indications of orBec® and Oral BDP

Based on its pharmacological characteristics, orBec®/oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have 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 HCT, as well as GVHD which also occurs following organ allograft transplantation. We also have an issued U.S. patent 7,704,985 claiming the use of oral BDP to treat IBS, a painful gastrointestinal condition that affects approximately 15% of the population in the industrialized world. 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 and European patent EP 1830857 claiming oral BDP in conjunction with a short duration of high-dose prednisone with a rapid taper for the reduction of mortality associated with GVHD and leukemia. We recently completed a Phase 2 trial of orBec® in the prevention of acute GVHD and announced preliminary results from this study. We are planning for a Phase 2 clinical trial in the treatment of chronic GI GVHD, pending further grant funding. We are exploring the possibility of testing oral BDP (the active ingredient in orBec®) for local inflammation associated with pediatric Crohn's Disease, Ulcerative Colitis, among other indications.

SGX201 - Oral BDP for Preventing Acute Radiation Enteritis

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. We recently completed a Phase 1/2 clinical trial testing SGX201 in prevention of acute radiation enteritis. Patients with rectal cancer who are 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 Research ("SBIR") grant awarded by the NIH. These data are currently under review 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. 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 an NDA for SGX201 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 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.

There are over 100,000 patients annually in the U.S. who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis.

SGX203 – Oral BDP for Treating Pediatric Crohn’s Disease

SGX203 is a two pill delivery system of a delayed release formulation of BDP specifically designed for oral use that allows for delivery 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. We plan to initiate a Phase 2 clinical trial in pediatric Crohn’s disease in 2012.

About Pediatric Crohn's Disease

Crohn's disease is an ongoing disorder that causes inflammation of the gastrointestinal (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 Ashkenazy 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. Pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the United States. Crohn's disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (25-40%) 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.

orBec® – Oral BDP for Preventing Acute GVHD

A trial was completed under an investigator-initiated Investigational New Drug ("IND") application by Paul Martin, MD, at the Fred Hutchinson Cancer Research Center. It was an exploratory, randomized, double blind, placebo-controlled, Phase 2 proof-of-concept clinical trial of orBec® for the prevention of acute GVHD in patients undergoing myeloablative conditioning regimens with initiation of dosing prior to hematopoietic cell transplantation (HCT) and continuing through the post-transplantation period. This study was supported, in large part, by a grant from the National Institutes of Health. We did not receive any direct monetary benefit from this grant.

The Phase 2 trial enrolled 140 patients with a 2:1 (orBec®:placebo) randomization plan. Results from this estimation study indicate that orBec® appears safe and well tolerated in this patient population, but did not achieve statistical significance in the primary endpoint, which was the proportion of patients who developed acute GVHD with severity sufficient to require systemic immunosuppressive treatment on or before day 90 after transplantation. This result was possibly due to poor patient compliance with administration of study drug which was lower than anticipated with only 54% of patients taking at least 90% of study drug within 4 weeks of transplantation. It was noted that poor compliance in the study may be associated with the incidence of oral mucositis, as a lower severity of oral mucositis was highly correlated with better compliance ($p < 0.0001$). Compliance was also better in patients who did not require systemic treatment for GVHD in the orBec® arm ($p = 0.001$) compared to those in the placebo arm ($p = 0.98$), consistent with the possibility that reduced adherence may have compromised the orBec® treatment effect. Among the 50 orBec® patients with at least 90% compliance, 54% required systemic treatment for GVHD, versus 65% of the 26 placebo patients with at least 90% compliance. The mean cumulative dose of prednisone was 28.8 mg/kg among all orBec® patients with at least 90% compliance, versus 37.1 mg/kg among all placebo patients with at least 90% compliance. For the group with less than 90% compliance, the mean cumulative prednisone dose was the same in both arms.

The use of orBec® also resulted in fewer cases of more severe acute GVHD grades IIb-IV (21% vs. 33% of patients receiving placebo), although this difference was not statistically significant. This result has the potential to be clinically relevant because GVHD grades IIb-IV are associated with more severe disease involving the skin and liver as well as being associated with poorer outcomes, including mortality rates that approach 100% in the grade IV patient population. The outcome of this study was published online in Biology of Blood and Marrow Transplantation (Martin et al., 2011, ASBMT:1-8).

LPM™ – Leuprolide for Endometriosis and Prostate Cancer

Our Lipid Polymer Micelle ("LPM™") oral drug delivery system is a proprietary platform technology designed to allow for the oral administration of peptide drugs that are water-soluble but poorly permeable through the gastrointestinal tract. We have previously demonstrated in pre-clinical animal models that the LPM™ technology is adaptable to oral delivery of peptide drugs and that high systemic levels after intestinal absorption can be achieved with the peptide

hormone drug leuprolide. The LPM™ system utilizes a lipid based delivery system that can incorporate the peptide of interest in a thermodynamically stable configuration called a “reverse micelle” that, through oral administration, can promote intestinal absorption. Reverse micelles are structures that form when certain classes of lipids come in contact with small amounts of water. This results in a drug delivery system in which a stable clear dispersion of the water soluble drug can be evenly dispersed within the lipid phase. LPM™ is thought to promote intestinal absorption due to the ability of the micelles to open up small channels through the epithelial layer of the intestines that allow only molecules of a certain dimension to pass through while excluding extremely large molecules such as bacteria and viruses. The reverse micelles also structurally prevent the rapid inactivation of peptides by enzymes in the upper gastrointestinal tract via a non-specific enzyme inhibition by surfactant(s) in the formulation.

In pre-clinical studies, the LPM™ delivery technology significantly enhanced the ability of leuprolide to pass through the intestinal epithelium in comparison to leuprolide alone. Leuprolide is a synthetic peptide agonist of gonadotropin releasing hormone, which is used in the treatment of prostate cancer in men and endometriosis in women. Leuprolide exhibits poor intestinal absorption from an aqueous solution with the oral bioavailability being less than 5%. Utilizing LPM™ in rats and dogs, the bioavailability of leuprolide averaged 30% compared to 2.2% for the control oral solution. Based on these promising pre-clinical data, we anticipate preparing for a Phase 1 study in humans to confirm these findings, pending further funding.

An oral version of leuprolide may provide a significant advantage over the currently marketed “depot” formulations. Leuprolide is one of the most widely used anti-cancer agents for advanced prostate cancer in men. Injectable forms of leuprolide marketed under trade names such as Lupron® and Eligard® had worldwide annual sales of more than $1 billion in recent years. Injectable leuprolide is also widely used in non-cancer indications, such as endometriosis in women (a common condition in which cells normally found in the uterus become implanted in other areas of the body), uterine fibroids in women (noncancerous growths in the uterus) and central precocious puberty in children (a condition causing children to enter puberty too soon). Leuprolide is currently available only in injectable, injectable depot and subcutaneous implant routes of delivery which limits its use and utility.

Vaccines/BioDefense Overview

ThermoVax™ - Thermostability Technology

Soligenix’s Thermostability technology, ThermoVax™, is a novel method of rendering aluminum salt, 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) reports that 50% of all vaccines around the world are wasted due to 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. On the Vaccines/BioDefense side, ThermoVax™ has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

Initial 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 over one month, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. Confirmatory results have extended the stability to more than three 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.

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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 60/896,429 filed on March 22, 2007 entitled "Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition." This patent and its 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.

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). 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.

Initial development work on VeloThrax™ has begun and will be conducted pursuant to Soligenix's $9.4 million NIAID grant enabling development of thermo-stable ricin and anthrax vaccines. 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, 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 from Infectious Disease Research Institute (IDRI) 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 Department of Defense (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.

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.

RiVax™ - Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first ricin. With RiVax™, Soligenix is 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. One Phase 1 human clinical trial was completed, and a second trial is currently being conducted. 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 is being supported by a grant from the FDA's Office of Orphan Products to UTSW. Soligenix and UTSW have collectively received approximately $15 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 the study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, PNAS, 105:2268-2273). The second trial, sponsored by UTSW, is currently evaluating a more potent formulation of RiVax™ that contains a conventional adjuvant (salts of aluminum), anticipated to result in higher antibody titers of longer duration in human subjects. This trial is expected to complete in the 2H 2012. Soligenix has adapted the original manufacturing process for the immunogen contained in RiVax™ for large scale manufacturing and is 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.

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.

OrbeShield™ – Oral BDP for Gastrointestinal Acute Radiation Syndrome (GI ARS)

OrbeShield™ (an oral immediate and delayed release formulation of the topically active corticosteroid beclomethasone dipropionate (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 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 radiation-induced GI ARS. 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.

The application of OrbeShield™ to acute GI ARS originated from other programs for oral BDP and is based on the properties of BDP to act locally in the GI to modulate local inflammation and epithelial cellular apoptosis. Development of OrbeShield™ for GI ARS is a natural extension of Soligenix's radiation enteritis clinical program with SGX201. Killing cancer cells with radiation therapy or chemotherapy must be done in ways that minimize toxicity to the rest of the body, but often leads to an inflammatory condition in the GI tract when administered in that general vicinity. In most radiation scenarios, injury to the hematopoietic (blood) system and GI tract are the main determinants of survival.

To date, development of OrbeShield™ has been largely supported by a $1 million NIH grant to Soligenix's academic partner, the Fred Hutchinson Cancer Research Center.

About GI ARS

The potential occurrence of industrial radiation accidents and the threat of terrorist events involving radioactive material mandate the development and implementation of effective treatments of radiation injury. The GI tract is highly sensitive to radiation damage. Substantial injury to the GI tract after radiation exposure results in death. In most radiation scenarios, injury to the hematopoietic system and gastrointestinal tract are the main determinants of survival. There is an urgent need to develop specific countermeasures against the lethality caused by intestinal exposure to radiation and against the pathophysiological manifestations of radiation-induced gastrointestinal 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.

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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. Licensing and associated milestone revenues are recorded when earned.

Accounting for Warrants

We considered FASB ASC 815, Evaluating Whether an Instrument is Considered Indexed to an Entity's Own Stock, which provides guidance for determining whether an equity-linked financial instrument (or embedded feature) issued by an entity is indexed to the entity's stock, and therefore, qualifying for the first part of the scope exception in paragraph 815-10-15. We evaluated the warrants' provisions and determined that they were indexed to our own stock and therefore to be accounted for as an equity instrument for the three months ended March 31, 2012 and 2011.

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 SEC, 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. The option's price is remeasured using the Black-Scholes model at the end of each quarterly reporting period. 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, 2012 Compared to March 31, 2011

For the three months ended March 31, 2012, we had a net loss of $1,438,755 as compared to a net loss of $1,720,411 for same period in the prior year, representing a reduction in the net loss of $218,656 or 16%.

For the three months ended March 31, 2012, revenues and associated costs relate to NIH grants awarded in support of our development of ricin and thermostable vaccines and orBec®. For the three months ended March 31, 2012, we had revenues of $647,418 as compared to $808,005 for the same period in the prior year, representing a decrease of $160,587, or 20%. The decreases in revenues were a result of decreases in NIH grant revenues and the development work underlying them.

We incurred costs related to those revenues for the three months ended March 31, 2012 and 2011 of $556,571 and $554,037, respectively, representing an increase of $2,534, or less than 1%. These costs relate to payments made to subcontractors in connection with research performed pursuant to the grants.

Our gross profit for the three months ended March 31, 2011 was $90,847, as compared to $253,968 for the same period in 2011, representing a decrease of $163,121, or 64%. The decrease in gross profit follows directly from the decreases in grant revenues discussed above, in same period prior year, gross profit included reimbursement of certain salary costs for which no corresponding cost had been incurred in the period.

Research and development spending decreased by $496,010, or 36%, to $876,794 for the three months ended March 31, 2012 as compared to $1,372,804 for the same period in 2011. During the three months ended March 31, 2012, we incurred expenses of $360,070 specifically related to orBec® studies. The decrease from the prior period is a result of the discontinuation of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD.

General and administrative expenses increased by $51,033, or 8%, to $655,043 for the three months ended March 31, 2012, as compared to $604,010 for the same period in 2011. Allocated salaries to general and administrative increased due to a reduction in the number specifically identifiable research and development programs.

Financial Condition

Cash and Working Capital

As of March 31, 2012, we had cash and cash equivalents of $5,321,133 as compared to $5,996,668 as of December 31, 2011, representing a decrease of $675,535 or 11%. As of March 31, 2012, we had working capital of $4,442,647 as compared to working capital of $5,696,444 as of December 31, 2011, representing a decrease of $1,253,797, or 22%.

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 2013.

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 will continue to reduce costs wherever possible.
- We have approximately $3.8 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 $574,157 in proceeds pursuant to NOL sales in 2011 we expect to participate in this expanded program during 2012 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 $3.3 million before any grant reimbursements, of which $1.2 million relates to the BioTherapeutics business and $2.1 million relates to the Vaccines/BioDefense business. We anticipate grant revenues in the next 12 months of approximately $2.2 million to offset research and development expenses, primarily for the development of our ThermoVax™ vaccine technology, and very limited contribution to the wind down costs of the Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD.

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

		2012		2011
Research & Development Expenses				
Oral BDP	$	360,070	$	786,577
RiVax™ and ThermoVax™ Vaccines		458,174		465,481
Oraprine™		-		1,500
LPM™-Leuprolide		-		2,577
Total	$	818,244	$	1,256,135
Reimbursed under NIH Grants				
orBec®	$	49,813	$	256,175
RiVax™ and thermostable vaccines		506,758		297,862
Total	$	556,571	$	554,037
Grand Total	$	1,374,815	$	1,810,172

Contractional Obligations

The Company has commitments of approximately $405,000 as of March 31, 2012 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 success will occur.

On April 1, 2009, the Company entered into a sublease agreement through March 31, 2012 for office space in Princeton, New Jersey. The Company was required to provide 4 months of rent as a security deposit. The rent for the first 18 months was approximately $7,500 per month, or approximately $17.00 per square foot on an annualized basis, for the remaining 18 months. 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, Mr. Myrianthopoulos' employment agreement was terminated. However, he continues to serve the Company as a member of the Board of Directors.

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	Severance	Total
2012	$ 105,000	$ 76,203	$ 101,425	$ 291,628
2013	75,000	104,559	-	179,559
2014	75,000	101,198	-	176,198
2015	75,000	24,938	-	99,938
2016	75,000	-	-	75,000
Total	$ 405,000	$ 306,898	$ 110,425	$ 822,323

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.

On February 15, 2012, the employment agreement of Mr. Myrianthopoulos, Chief Financial Officer and Senior Vice-President was terminated and Mr. Joseph M. Warusz was appointed the Acting Chief Financial Officer.

PART II - OTHER INFORMATION.

ITEM 1A – RISK FACTORS

You should carefully consider the risks, uncertainties and other factors described below before you decide whether to buy shares of our common stock. Any of the factors could materially and adversely affect our business, financial condition, operating results and prospects and could negatively impact the market price of our common stock. Below are the significant risks and uncertainties of which we are aware. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations. You should also refer to the other information contained in this Quarterly Report.

Risks Related to our Business

We have had significant losses and anticipate future losses; if additional funding cannot be obtained, we may reduce or discontinue our product development and commercialization efforts.

We have experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. As of March 31, 2012, we have approximately $5.3 million in cash available. Based on our projected budgetary needs and funding from existing grants over the next two years, we expect to be able to maintain the current level of our operations into the second quarter of 2013.

We have sufficient funds through our existing biodefense grant facilities from the National Institute of Allergy and Infectious Diseases (“NIAID”), a division of the National Institutes of Health (“NIH”), to finance our biodefense projects for the next several years. In September 2009, we received a NIAID grant for approximately $9.4 million for the development of our biodefense programs. Our biodefense grants have an overhead component that allows us an agency-approved percentage over our incurred costs. We estimate that the overhead component, which is approximately 21% above our subcontracted expenses, will finance some fixed costs for direct employees working on the grants and other administrative costs. We expect that our existing NIH biodefense grants will cover approximately $600,000 of such fixed overhead costs over the next several years.

Our products are positioned for or are currently in clinical trials, and we have not yet generated any significant revenues from sales or licensing of them. From inception through March 2012, we have expended approximately $45.0 million developing our current product candidates for pre-clinical research and development and clinical trials, and we currently expect to spend at least $2 million over the next two years in connection with the development of our therapeutic and vaccine products, licenses, employment agreements, and consulting agreements. Unless and until we are able to generate sales or licensing revenue from one of our product candidates, we will require additional funding to meet these commitments, sustain our research and development efforts, provide for future clinical trials, and continue our operations. There can be no assurance we can raise such funds. If additional funds are raised through the issuance of equity securities, stockholders may experience dilution of their ownership interests, and the newly issued securities may have rights superior to those of the common stock. If additional funds are raised by the issuance of debt, we may be subject to limitations on our operations. If we cannot raise such additional funds, we may have to delay or stop some or all of our drug development programs.

If we are unsuccessful in developing our products, our ability to generate revenues will be significantly impaired.

To be profitable, our organization must, along with corporate partners and collaborators, successfully research, develop and commercialize our technologies or product candidates. Our current product candidates are in various stages of clinical and pre-clinical development and will require significant further funding, research, development, pre-clinical and/or clinical testing, regulatory approval and commercialization, and are subject to the risks of failure inherent in the development of products based on innovative or novel technologies. Specifically, each of the following is possible with respect to any of our product candidates:

- we may not be able to maintain our current research and development schedules;
- we may be unsuccessful in our efforts to secure profitable procurement contracts from the U.S. government or others for our biodefense products;
- we may encounter problems in clinical trials; or
- the technology or product may be found to be ineffective or unsafe.

If any of the risks set forth above occur, or if we are unable to obtain the necessary regulatory approvals as discussed below, we may not be able to successfully develop our technologies and product candidates and our business will be seriously harmed. Furthermore, for reasons including those set forth below, we may be unable to commercialize or receive royalties from the sale of any other technology we develop, even if it is shown to be effective, if:

- it is not economical or the market for the product does not develop or diminishes;
- we are not able to enter into arrangements or collaborations to manufacture and/or market the product;
- the product is not eligible for third-party reimbursement from government or private insurers;
- others hold proprietary rights that preclude us from commercializing the product;
- we are not able to manufacture the product reliably;
- others have brought to market similar or superior products; or
- the product has undesirable or unintended side effects that prevent or limit its commercial use.

Our confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease (“GI GVHD”) was stopped on September 15, 2011 at the recommendation of an independent Data Safety Monitoring Board (“DSMB”).

Our business is subject to very stringent U.S., federal, foreign, state and local government laws and regulations, including the Federal Food, Drug and Cosmetic Act, the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these acts. These laws and regulations may be amended, additional laws and regulations may be enacted, and the policies of the FDA and other regulatory agencies may change.

On October 18, 2007, we received a “not approvable letter” from the FDA for our lead product candidate, orBec®, for the treatment of acute GI GVHD. The letter stated that the FDA requested data from additional clinical trials to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of the not approvable letter. On October 19, 2007, we requested an “End of Review Conference” with the FDA to further understand the letter and gain clarity regarding the next steps. On December 7, 2007, we announced the following guidance from that meeting: (1) a single, confirmatory, Phase 3 clinical trial could provide sufficient evidence of efficacy provided that it is well designed, well executed and provides clinically and statistically meaningful findings; (2) we anticipated working quickly with the FDA to finalize the design of the confirmatory trial under the Agency’s “Special Protocol Assessment” process; and (3) the FDA would be agreeable to reviewing a plan for a Treatment Investigational New Drug (“Treatment IND”) as long as it does not interfere with patient accrual in a confirmatory trial, such as potentially enrolling patients that would not be eligible for the Phase 3 study.

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On January 5, 2009, we reached an agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating our lead product orBec® for the treatment of acute GI GVHD. The agreement was made under the FDA's Special Protocol Assessment procedure. The confirmatory Phase 3 clinical trial for the treatment of acute GI GVHD commenced on October 15, 2009. The trial was stopped on September 15, 2011 at the recommendation of the DSMB because it is highly unlikely to achieve the predetermined end point of efficacy based on the interim results. Preliminary findings indicate that there are no significant differences between the orBec® group and placebo group for the primary endpoint, as well as for the pre-specified secendary endpoints. Given the outcome of the Phase 3 study, the Company will be terminating the development of orBec® for the treatment of acute GI GVHD.

Although we hope to obtain FDA approval for orBec® in GVHD, there can be no assurances that the FDA will ever approve orBec® for market launch.

Our business is subject to extensive governmental regulation, which can be costly, time consuming and subjects us to unanticipated delays.

The regulatory process applicable to our products requires pre-clinical and clinical testing of any product to establish its safety and efficacy. This testing can take many years and require the expenditure of substantial capital and other resources. We may not be able to obtain, or we may experience difficulties and delays in obtaining, necessary domestic and foreign governmental clearances and approvals to market a product. Also, even if regulatory approval of a product is granted, that approval may entail limitations on the indicated uses for which the product may be marketed.

Following any regulatory approval, a marketed product and its manufacturer are subject to continual regulatory review. Later discovery of problems with a product or manufacturer may result in restrictions on such product or manufacturer. These restrictions may include withdrawal of the marketing approval for the product. Furthermore, the advertising, promotion and export, among other things, of a product are subject to extensive regulation by governmental authorities in the U.S. and other countries. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and/or criminal prosecution.

There may be unforeseen challenges in developing our biodefense products.

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

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We will be dependent on government funding, which is inherently uncertain, for the success of our biodefense operations.

We are subject to risks specifically associated with operating in the biodefense industry, which is a new and unproven business area. We do not anticipate that a significant commercial market will develop for our biodefense products. Because we anticipate that the principal potential purchasers of these products, as well as potential sources of research and development funds, will be the U.S. government and governmental agencies, the success of our biodefense division will be dependent in large part upon government spending decisions. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, all of which are inherently uncertain and may be affected by changes in U.S. government policies resulting from various political and military developments. Our successful receipt of government funding is also dependant on our ability to adhere to the terms and provisions of the original grant documents and other regulations.

If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products. We do not have or are anticipating having internal manufacturing capabilities.

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards, which material will be used in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

The manufacture of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with current Good Manufacturing Practice (“cGMP”) or similar requirements that the FDA or foreign regulators establish. We, or our materials suppliers, may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA’s cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing some of our product candidates.

We do not have experience in marketing or selling pharmaceutical products whether in the U.S. or internationally. Although we have a collaboration agreement with Sigma-Tau for the sales and marketing of orBec® in North America and Europe, we may be unable to establish additional satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for orBec® or our other product candidates. In addition, Sigma-Tau may not be able to effectively commercialize orBec® if it is approved. To obtain the expertise necessary to successfully market and sell orBec®, or any other product, potentially will require the development of our own commercial infrastructure and/or collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract.

Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations.

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

Federal and/or state health care reform initiatives could negatively affect our business.

The availability of reimbursement by governmental and other third-party payers affects the market for any pharmaceutical product. These third-party payers continually attempt to contain or reduce the costs of healthcare. There have been a number of legislative and regulatory proposals to change the healthcare system and further proposals are likely. Medicare's policies may decrease the market for our products. Significant uncertainty exists with respect to the reimbursement status of newly approved healthcare products.

In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Once approved, we might not be able to sell our products profitably or recoup the value of our investment in product development if reimbursement is unavailable or limited in scope, particularly for product candidates addressing small patient populations.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

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On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms to establish a bundled Medicare payment rate that includes services and drug/labs that are currently separately billed. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. We cannot speculate on the potential sales impact to orBec® based on the new rule.

We may not be able to retain rights licensed to us by third parties to commercialize key products or to develop the third party relationships we need to develop, manufacture and market our products.

We currently rely on license agreements from the University of Texas Southwestern Medical Center, Harvard University, the University of Colorado, and George B. McDonald, MD for the rights to commercialize key product candidates. We may not be able to retain the rights granted under these agreements or negotiate additional agreements on reasonable terms, or at all.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop and test our product candidates, we need to contract or partner with outside researchers, in most cases with or through those parties that did the original research and from whom we have licensed the technologies. If products are successfully developed and approved for commercialization, then we will need to enter into additional collaboration and other agreements with third parties to manufacture and market our products. We may not be able to induce the third parties to enter into these agreements, and, even if we are able to do so, the terms of these agreements may not be favorable to us. Our inability to enter into these agreements could delay or preclude the development, manufacture and/or marketing of some of our product candidates or could significantly increase the costs of doing so. In the future, we may grant to our development partners rights to license and commercialize pharmaceutical and related products developed under the agreements with them, and these rights may limit our flexibility in considering alternatives for the commercialization of these products. Furthermore, third-party manufacturers or suppliers may not be able to meet our needs with respect to timing, quantity and quality for the products.

Additionally, if we do not enter into relationships with additional third parties for the marketing of our products, if and when they are approved and ready for commercialization, we would have to build our own sales force. If our collaboration agreement with Sigma-Tau were to be terminated, we would need to establish and build our own sales force in North America and Europe or enter into an agreement for the commercialization of orBec® with another company. Development of an effective sales force in any part of the world would require significant financial resources, time and expertise. We may not be able to obtain the financing necessary to establish a sales force in a timely or cost effective manner, if at all, and any sales force we are able to establish may not be capable of generating demand for our product candidates, if they are approved.

We may suffer product and other liability claims; we maintain only limited product liability insurance, which may not be sufficient.

The clinical testing, manufacture and sale of our products involves an inherent risk that human subjects in clinical testing or consumers of our products may suffer serious bodily injury or death due to side effects, allergic reactions or other unintended negative reactions to our products. As a result, product and other liability claims may be brought against us. We currently have clinical trial and product liability insurance with limits of liability of $5 million, which may not be sufficient to cover our potential liabilities. Because liability insurance is expensive and difficult to obtain, we may not be able to maintain existing insurance or obtain additional liability insurance on acceptable terms or with adequate coverage against potential liabilities. Furthermore, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity.

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We may not be able to compete successfully with our competitors in the biotechnology industry.

The biotechnology industry is intensely competitive, subject to rapid change and sensitive to new product introductions or enhancements. Most of our existing competitors have greater financial resources, larger technical staffs, and larger research budgets than we have, as well as greater experience in developing products and conducting clinical trials. Our competition is particularly intense in the gastroenterology and transplant areas and is also intense in the therapeutic area of inflammatory bowel diseases. We face intense competition in the biodefense area from various public and private companies and universities as well as governmental agencies, such as the U.S. Army, which may have their own proprietary technologies that may directly compete with our technologies. In addition, there may be other companies that are currently developing competitive technologies and products or that may in the future develop technologies and products that are comparable or superior to our technologies and products. We may not be able to compete successfully with our existing and future competitors.

We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.

Our success depends in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and recently has been the subject of much litigation. Any patents we have obtained, or may obtain in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the U.S. Patent and Trademark Office regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the U.S. are maintained in secrecy until patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The Patent and Trademark Office may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our patented technologies may infringe on patents or other rights owned by others, licenses to which may not be available to us. We may not be successful in our efforts to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

Our business could be harmed if we fail to retain our current personnel or if they are unable to effectively run our business.

We currently have only 9 employees and we depend upon these employees to manage the day-to-day activities of our business. Because we have such limited personnel, the loss of any of them or our inability to attract and retain other qualified employees in a timely manner would likely have a negative impact on our operations. We will not be successful if our management team cannot effectively manage and operate our business.

Instability and volatility in the financial markets could have a negative impact on our business, financial condition, results of operations, and cash flows.

During recent months, there has been substantial volatility and a decline in financial markets due at least in part to the deteriorating global economic environment. In addition, there has been substantial uncertainty in the capital markets and access to additional financing is uncertain. Moreover, customer spending habits may be adversely affected by the current economic crisis. These conditions could have an adverse effect on our industry and business, including our financial condition, results of operations, and cash flows.

To the extent that we do not generate sufficient cash from operations, we may need to issue stock or incur indebtedness to finance our plans for growth. Recent turmoil in the credit markets and the potential impact on the liquidity of major financial institutions may have an adverse effect on our ability to fund our business strategy through borrowings, under either existing or newly created instruments in the public or private markets on terms we believe to be reasonable, if at all.

Risks Related to our Common Stock

Our common stock price is highly volatile.

The market price of our common stock, like that of many other research and development public pharmaceutical and biotechnology companies, has been highly volatile and may continue to be so in the future due to a wide variety of factors, including:

- announcements by us or others of results of pre-clinical testing and clinical trials;
- announcements of technological innovations, more important bio-threats or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our quarterly operating results and performance;
- developments or disputes concerning patents or other proprietary rights;
- acquisitions;
- litigation and government proceedings;
- adverse legislation;
- changes in government regulations;
- our available working capital;
- economic and other external factors; and

- general market conditions.

Since January 1, 2012, the closing stock price (split adjusted) has fluctuated over the last year between a high of $0.80 per share to a low of $0.33 per share. As of May 10, 2012, our common stock closed at $0.35 per share. The fluctuation in the price of our common stock has sometimes been unrelated or disproportionate to our operating performance. In addition, potential dilutive effects of future sales of shares of common stock by the Company, and subsequent sale of common stock by the holders of warrants and options, could have an adverse effect on the market price of our shares.

Our common stock trades on the Over-the-Counter Bulletin Board.

Our common stock trades on the Over-The-Counter Bulletin Board ("OTCBB") securities market under the symbol "SNGX." The OTCBB is a decentralized market regulated by the Financial Industry Regulatory Authority in which securities are traded via an electronic quotation system that serves more than 3,000 companies. On the OTCBB, securities are traded by a network of brokers or dealers who carry inventories of securities to facilitate the buy and sell orders of investors, rather than providing the order matchmaking service seen in specialist exchanges. OTCBB securities include national, regional, and foreign equity issues. Companies traded on the OTCBB must be current in their reports filed with the Securities and Exchange Commission ("SEC") and other regulatory authorities.

If our common stock is not listed on a national exchange or market, the trading market for our common stock may become illiquid. Our common stock is subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than $5.00 per share, other than securities registered on certain national securities exchanges provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, before a transaction in a penny stock that is not otherwise exempt from such rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. As a result of these requirements, our common stock could be priced at a lower price and our stockholders could find it more difficult to sell their shares.

Shareholders may suffer substantial dilution related to issued stock warrants and options.

We have a number of agreements or obligations that may result in dilution to investors. These include:

- warrants to purchase a total of approximately 2,576,341 shares of our common stock at a current weighted average exercise price of approximately $4.40; and
- options to purchase approximately 1,496,898 shares of our common stock at a current weighted average exercise price of approximately $3.72.

To the extent that warrants or options are exercised, our stockholders will experience dilution and our stock price may decrease.

Our shares of common stock are thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our common stock has from time to time been "thinly-traded," meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This

situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 5,250 square feet of office space at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540. This office space currently serves as our corporate headquarters. We currently pay rent of approximately $7,650 per month, or approximately $17.50 per square foot on an annualized basis, pursuant to the lease that we entered into on April 1, 2009 and that expires on March 31, 2012. Our office space is sufficient to satisfy our current needs. 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.

Item 3. Legal Proceedings

From time to time, we are a party to claims and legal proceedings arising in the ordinary course of business. Our management evaluates our exposure to these claims and proceedings individually and in the aggregate and allocates additional monies for potential losses on such litigation if it is possible to estimate the amount of loss and if the amount of the loss is probable. We are not a party to any legal proceedings at this time.

We have identified no significant additional risk factors other than those highlighted above which were included in Part I, Item 1A of our Form 10-K for the fiscal year ended December 31, 2011. 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 6 - EXHIBITS

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.

SIGNATURES

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

SOLIGENIX, INC.

May 14, 2012	by	/s/ Christopher J. Schaber
		Christopher J. Schaber, PhD President and Chief Executive Officer (Principal Executive Officer)
May 14, 2012	by	/s/ Joseph M. Warusz