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

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

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2013

or

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

For the transition period from _____ to _____

Commission File No. 000-16929

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

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

(609) 538-8200
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web Site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of “accelerated filer” and “large accelerated filer” in Rule 112b-2 of the Exchange Act.

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

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

As of May 01, 2013, 12,231,492 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

SOLIGENIX, INC.

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PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc. and Subsidiaries
Consolidated Balance Sheets

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

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Three Months Ended March 31, 2013 and 2012
(Unaudited)

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

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

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

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

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Three Months Ended March 31,
(Unaudited)

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

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

Soligenix, Inc.
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the "Company," "we" or "us") is a clinical stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense. Soligenix's BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis. Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, and VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome ("GI ARS") therapeutic. The advanced development of these vaccine programs is currently supported by the Company's heat stabilization technology, known as ThermoVax™, under existing and on-going grant funding.

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

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with FDA regulations, litigation, and product liability. Results for the quarter ended March 31, 2013 are not necessarily indicative of results that may be expected for the full year.

Liquidity

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

Management's business strategy can be outlined as follows:

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

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

Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic GI GVHD;

Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology, known as ThermoVax™, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

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

Explore other business development and acquisition strategies.

Based on the Company's current rate of cash outflows, cash on hand and proceeds from its grant programs, and proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the second quarter of 2014.

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

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

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

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

The Company will pursue sale of Net Operating Losses ("NOLs") in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $521,458 in proceeds pursuant to NOL sales in 2012, the Company expects to participate in the program during 2013 and beyond; and

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

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Operating Segments

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

Grants Receivable

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

Intangible Assets

One of the most significant estimates or judgments that the Company makes is whether to capitalize or expense patent and license costs. The Company makes this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, Research and Development. Based on this consideration, the Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for its current products in both the domestic and international markets. The Company believes that patent rights are one of its most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from Soligenix's academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its products at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents and perhaps extending the lives of the patents. The Company capitalizes such costs and amortizes intangibles over their expected useful life – generally a period of 11 to 16 years.

The Company did not incur any capitalizable patent related costs during the quarters ended March 31, 2013 and 2012.

Impairment of Long-Lived Assets

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

The Company did not record any impairment of long-lived assets for the quarters ended March 31, 2013 and 2012.

Fair Value of Financial Instruments

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

Revenue Recognition

Principally the Company's revenues are generated from NIH grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). Recording of revenue is applied in accordance with FASB ASC 605, Revenue Recognition, ASC 605-25 and/or Accounting Standard Update, ASU, 2009-13, Revenue Recognition – Multiple Element Arrangements. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant.

Research and Development Costs

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

Stock-Based Compensation

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

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

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

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

The fair value of options to be granted are estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option’s vesting periods, which approximates the service period.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company’s current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through March 31, 2013 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2013 and 2012. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a

liability for uncertain tax positions at March 31, 2013 and 2012. Tax years beginning in 2010 for federal purposes are generally subject to examination by taxing authorities, although net operating losses from those years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

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

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

Use of Estimates and Assumptions

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

Note 3. Intangible Assets

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

	Weighted Average Remaining Amortization Period (years)	Cost	Accumulated Amortization	Net Book Value
March 31, 2013				
Licenses	7.5	$ 462,234	$ 258,737	$ 203,497
Patents	3.2	1,893,185	1,295,997	597,188
Total	4.0	$ 2,355,419	$ 1,554,734	$ 800,685
December 31, 2012				
Licenses	7.7	$ 462,234	$ 252,019	$ 210,215
Patents	3.3	1,893,185	1,247,672	645,513
Total	4.2	$ 2,355,419	$ 1,499,691	$ 855,728

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

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

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

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

Note 4. Income Taxes

The Company had NOLs at December 31, 2012 of approximately $79,463,000 for federal tax purposes and approximately $9,498,000 of New Jersey NOL carry forwards remaining after the sale of unused NOL carry forwards, portions of which are currently expiring each year until 2031. In addition, the Company had $3,068,000 of various tax credits that started expiring in December 2012 and will continue to expire through December 2030. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code ("IRC") Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is possible that the utilization of the NOLs, could be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to Federal income tax assessment for years before 2010 for Federal and 2009 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination and adjustments by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

The Company has no tax provision for the three month periods ended March 31, 2013 and 2012 due to losses and full valuation allowances against net deferred tax assets.

Note 5. Shareholders' Equity

Preferred Stock

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

Common Stock

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

Note 6. Commitments and Contingencies

The Company has commitments of approximately $368,800 as of March 31, 2013 for several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

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

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

obligation to issue such shares if such event occurs.

Employees with employment contracts have severance agreements that will provide separation benefits from the Company if they are involuntarily separated from employment. The Company recognized an expense of $95,625 during the quarter ended March 31, 2012 related to severance and healthcare benefits paid to the prior Chief Financial Officer of the Company.

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

Year	Research and Development	Property and Other Leases	Total
2013	$ 43,800	$ 79,100	$ 122,900
2014	100,000	101,200	201,200
2015	75,000	25,000	100,000
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	$ 368,800	$ 205,300	$ 574,100

Note 7. Operating Segments

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

	Three Months Ended March 31,	
	2013	2012
Grant Revenue		
Vaccines/BioDefense	$829,849	$597,605
BioTherapeutics	70,505	49,813
Total	$900,354	$647,418
Loss from Operations		
Vaccines/BioDefense	$(30,995)	$(128,366)
BioTherapeutics	(457,625)	(726,042)
Corporate	(599,277)	(586,582)
Total	$(1,087,897)	$(1,440,990)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$27,667	$27,997
BioTherapeutics	28,395	28,840
Corporate	436	507
Total	$56,498	$57,344
Interest Income		
Corporate	$483	$2,235
Stock-Based Compensation		
Vaccines/BioDefense	$11,121	$2,130
BioTherapeutics	21,036	56,240
Corporate	47,335	59,064
Total	$79,492	$117,614

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

Note 8. Subsequent Event

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

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

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes, Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2012. This report contains forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expressions, however, these words are exclusive means of identifying such statements. In addition, any statements that refer to expectations projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the U.S. Securites and Exchage Commission or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures the Company makes in this report and our other reports filed with the U.S. Securites and Exchage Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Overview:

Business Overview

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

Our BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203), acute radiation enteritis, (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome ("GI ARS") therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVax™, under existing and on-going government grant funding.

An outline for our business strategy follows:

- Initiate a Phase 1/2 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn's disease;
- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic graft-versus-host disease ("GI GVHD");
- Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology, known as ThermoVax™, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

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

Explore other business development and acquisition strategies.

We were incorporated in Delaware in 1987. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Our Products in Development

The following tables summarize the products that we are currently developing:

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX942	Oral Mucositis in Head and Neck Cancer	IND clearance and Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical trial planned for the first half of 2013, with data expected in the first half of 2013; Phase 2/3 clinical trial planned for the second half of 2013, with data expected in the second half of 2014
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated Phase 2 trial planned for the first half of 2014, with data expected in the first half of 2015
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014

Vaccine Thermostability Platform

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

BioDefense Products

Soligenix Product	Indication	Stage of Development

RiVax™	Vaccine against Ricin Toxin Poisoning	Phase 1B trial complete; safety and neutralizing antibodies for protection demonstrated Phase 2 trial planned for the first half of 2014
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical; Phase 1 clinical trial planned for second half of 2014
OrbeShield™	Therapeutic against GI ARS	Follow-on pre-clinical study initiated; Initial pre-clinical study complete; protection observed in canine

BioTherapeutics Overview

SGX94

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

SGX94 is the research name for the active ingredient in SGX942, which is the research name for the finished drug product being studied in oral mucositis. It is a new class of short, synthetic peptides known as IDRs that have a novel mechanism of action in that it is simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. IDRs provide a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, sequestosome-1, also known as p62, which has a pivotal function in signal transduction during activation and control of the innate defense system. Preclinical data indicate that IDRs are active in models of a wide range of therapeutic indications including life-threatening bacterial infections as well as the severe side-effects of chemo- and radiation-therapy.

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

SGX94 has demonstrated efficacy in numerous animal disease models including mucositis, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. SGX94 showed a strong safety profile when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. SGX94 is the subject of an open Investigational New Drug ("IND") application which has been cleared by the FDA. Market opportunities include, but are not limited to, mucositis, acute bacterial skin and skin structure infections, acinetobacter, melioidosis, acute radiation syndrome and as a vaccine adjuvant, with potential opportunities for non-dilutive funding to support the development.

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

SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

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

About Oral Mucositis

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

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

We estimate, based upon our review of published studies and reports, that oral mucositis is a subpopulation of approximately 90,000 patients in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (>80% incidence of severe mucositis) and is common (40-100% incidence) in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

Oral BDP

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

Based on its pharmacological characteristics, oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent 8,263,582 claiming the use of oral BDP as a method of treating inflammatory disorders of the gastrointestinal tract, including Crohn's disease, and an issued U.S. patent 6,096,731 claiming the use of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD following hematopoietic cell transplantation ("HCT"), as well as GVHD which also occurs following organ allograft transplantation. We also have European Patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract. We are planning to pursue development programs in the treatment of pediatric Crohn's disease, acute radiation enteritis, chronic GI GVHD, and GI ARS pending further grant funding. We are also exploring the possibility of testing oral BDP for local inflammation associated with Ulcerative Colitis, among other indications.