SOLIGENIX, INC.
Form 10-Q
November 14, 2011

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 September 30, 2011

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 (Address of principal executive offices)	08540 (Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web Site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes x No o

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

Exchange Act (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 November 7, 2011, 220,985,710 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)

	September 30, 2011	December 31, 2010*
Assets		
Current assets:		
Cash and cash equivalents	$ 7,218,275	$ 7,451,714
Grants receivable	297,847	120,787
Other receivable	-	251,864
Prepaid expenses	154,670	187,494
Total current assets	7,670,792	8,011,859
Office furniture and equipment, net	16,813	20,699
Intangible assets, net	1,227,497	1,235,989
Total assets	$ 8,915,102	$ 9,268,547
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,371,943	$ 1,674,175
Accrued compensation	41,894	236,581
Total current liabilities	1,413,837	1,910,756
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 5,000,000 shares authorized; none issued or outstanding	-	-
Common stock, $.001 par value; 400,000,000 shares authorized; 220,985,710 shares and 216,192,360 shares issued and outstanding in 2011 and 2010, respectively	220,986	216,192
Additional paid-in capital	124,465,912	122,880,378
Accumulated deficit	(117,185,633)	(115,738,779)
Total shareholders' equity	7,501,265	7,357,791
Total liabilities and shareholders' equity	$ 8,915,102	$ 9,268,547

The accompanying notes are an integral part of these consolidated financial statements.
* Derived from audited information

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Three and Nine Months Ended September 30, 2011 and 2010
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
License revenue	$5,000,000	$-	$5,000,000	$-
Grant revenue	795,862	860,517	2,009,687	1,640,955
Total revenues	5,795,862	860,517	7,009,687	1,640,955
Cost of revenues	(655,125)	(779,396)	(1,558,673)	(1,402,262)
Gross profit	5,140,737	81,121	5,451,014	238,693
Operating expenses:				
Research and development	2,342,253	1,276,550	5,228,779	4,025,703
General and administrative	595,021	543,086	1,674,408	1,668,402
Total operating expenses	2,937,274	1,819,636	6,903,187	5,694,105
Income (Loss) from operations	2,203,463	(1,738,515)	(1,452,173)	(5,455,412)
Other income:				
Interest income, net	1,411	4,775	5,319	8,120
Net income (loss)	$2,204,874	$(1,733,740)	$(1,446,854)	$(5,447,292)
Basic and diluted net income (loss) per share	$0.01	$(0.01)	$(0.01)	$(0.03)
Basic and diluted weighted average common shares outstanding	220,272,322	215,869,026	218,412,968	197,818,925

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 Nine Months Ended September 30, 2011
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2010	216,235,262	$216,235	$122,880,335	$(115,738,779)	$7,357,791
Issuance of common stock pursuant to equity line agreement – Fusion	1,815,780	1,816	353,184	-	355,000
Issuance of common stock for stock option and warrant exercises	1,596,875	1,597	252,016	-	253,613
Issuance of common stock pursuant amended license agreement	1,337,793	1,338	398,662	-	400,000
Fair value of common stock warrants to vendors	-	-	11,184	-	11,184
Settlement of broker fees associated with 2010 financing	-	-	40,743	-	40,743
Stock-based compensation expense	-	-	529,788	-	529,788
Net loss				(1,446,854)	(1,446,854)
Balance, September 30, 2011	220,985,710	$220,986	$124,465,912	$(117,185,633)	$7,501,265

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Nine Months Ended September 30,
(Unaudited)

	2011	2010
Operating activities:		
Net loss	$(1,446,854)	$(5,447,292)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	165,042	135,270
Common stock issued for amended license agreement	400,000	-
Common stock or warrants issued in exchange for services	11,184	171,890
Stock-based compensation	529,788	463,909
Capitalized patent write-off	-	378,501
Change in operating assets and liabilities:		
Grants receivable	(177,060)	(190,559)
Other receivable	251,864	-
Inventory	-	42,865
Prepaid expenses	32,824	(83,458)
Accounts payable	(302,232)	646,682
Accrued compensation	(194,687)	(326,440)
Total adjustments	716,723	1,238,660
Net cash used in operating activities	(730,131)	(4,208,632)
Investing activities:		
Acquisition of intangible assets	(151,086)	(257,598)
Purchase of office equipment	(1,578)	(6,261)
Net cash used in investing activities	(152,664)	(263,859)
Financing activities:		
Net proceeds from sale of common stock	-	5,679,856
Settlement of Broker Fees associated with 2010 Financing	40,743	-
Proceeds from sale of common stock pursuant to equity line	355,000	70,000
Proceeds from exercise of options and warrants	253,613	58,852
Net cash provided by financing activities	649,356	5,808,708
Net (decrease)/ increase in cash and cash equivalents	(233,439)	1,336,217
Cash and cash equivalents at beginning of period	7,451,714	7,692,011
Cash and cash equivalents at end of period	$7,218,275	$9,028,228

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

Soligenix, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. ("Soligenix," 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"). Soligenix's Vaccines/BioDefense business segment intends to use RiVaxTM, its ricin toxin vaccine, to support development efforts with its heat stabilization technology, and SGX202, its gastrointestinal acute radiation syndrome ("GI ARS") program, to convert from early stage development to advanced development with the assistance of ongoing government grant funding.

The Company currently 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.

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States of America. The accompanying consolidated financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements have been condensed or omitted from this report, as is permitted by such rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. The unaudited consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 as filed with the SEC on March 29, 2011. Results for interim periods are not necessarily indicative of results for the full year. The Company has experienced significant quarterly fluctuations in operating results and it expects those fluctuations will continue.

Liquidity

As of September 30, 2011, the Company had cash and cash equivalents of $7,218,275 as compared to $7,451,714 as of December 31, 2010, representing a decrease of $233,439. As of September 30, 2011, the Company had working capital of $6,256,955 as compared to working capital of $6,101,103 as of December 31, 2010, representing an increase of $155,852 or 3%. Based on our current cash on hand, which includes the $5,000,000 of proceeds from Sigma-Tau and proceeds from our grant-funded programs, 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.

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Management's business plans can be outlined as follows:

- Evaluate the data from the recently terminated confirmatory Phase 3 clinical trial of orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD") and determine how to proceed;
- Use RiVaxTM to support development efforts and establish proof of concept with the heat stabilization technology SGX205;
- Complete and report data from the Phase 1/2 clinical trial for SGX201 (oral BDP) in the prevention of acute radiation enteritis;
- Evaluate and consider initiating additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as GI ARS, radiation enteritis, Crohn's disease, prevention of acute GVHD, and treatment of chronic GI GVHD;
- Continue to secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;
- Acquire or in-license new clinical-stage compounds for development; and
- Explore other business development and acquisition strategies.

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 $6.8 million in active grant funding still available to support its associated research programs through 2013 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 Net Operating Losses ("NOL") sales in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $245,810 in proceeds pursuant to NOL sales in 2010, the Company has submitted the program application and expects to participate in the expanded program during 2011 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.

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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 our 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 designed to protect, preserve, maintain and perhaps extend 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 capitalized $151,086 and $257,598 in patent related costs during the nine months ended September 30, 2011 and 2010, respectively.

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 nine months ended September 30, 2011 or 2010.

Revenue Recognition

Principally the Company's revenues are generated from NIH grants. The Company also generates 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. Licensing activities and the achievement of licensing milestone revenues are recorded when earned. As a result of stopping the

confirmatory Phase 3 clinical trial on September 15, 2011 as well as no future clinical development obligations associated with the Sigma-Tau Agreement, the Company recognized license revenue of $5,000,000 relating to the execution of an expanded license agreement with Sigma-Tau for the European territory.

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.

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.

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;
- volatilities of 123% and 129% for 2011 and 2010, respectively;
- forfeitures at a rate of 12%; and
- risk-free interest rates of 1.21% and 1.91% in 2011 and 2010, respectively.

The Company estimates these values based on the assumptions that have been historically available. The fair value of each option grant made during 2011 and 2010 was estimated on the date of each grant using the Black-Scholes option pricing model and is then amortized ratably over the option’s vesting periods, which approximates the service period.

There were 1,596,875 options exercised and 1,640,625 options expired or were forfeited during the 9 months ended September 30, 2011. As of September 30, 2011, the Company has 26,340,427 outstanding options of which 21,001,201 are vested to their respective employees and director grantees.

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 September 30, 2011 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 2011 and 2010. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at September 30, 2011 or December 31, 2010. 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. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented. No options and warrants were included in the 2011 and 2010 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 September 30,					
	2011			2010		
	Net Income	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	$2,204,874	220,272,322	$0.01	$(1,773,740)	215,869,026	$(0.01)

	Nine Months Ended September 30,					
	2011			2010		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	$(1,446,854)	218,412,968	$(0.01)	$(5,447,292)	197,818,925	$(0.03)

Shares issuable upon the exercise of options and warrants outstanding at September 30, 2011 and 2010 were 26,340,427 and 26,986,039 shares issuable upon the exercise of options, and 54,156,373 and 54,431,373 shares issuable upon the exercise of warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at September 30, 2011 were $0.24 and $0.22 per share, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at September 30, 2010 were $0.24 and $0.22 per share, respectively.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as warrants, stock options and 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
September 30, 2011				
Licenses	9.0	$462,234	$ 217,842	$244,392
Patents	3.8	2,063,870	1,080,765	983,105
Total	4.7	$2,526,104	$ 1,298,607	$1,227,497
December 31, 2010				
Licenses	9.7	$462,234	$ 197,469	$264,765
Patents	4.2	1,912,784	941,559	971,224
Total	5.3	$2,375,018	$ 1,139,028	$1,235,989

Amortization expense was $57,734 and $47,870 for the three months ended September 30, 2011 and 2010, respectively and $159,578 and $130,366 for the nine months ended September 30, 2011 and 2010, respectively. For the nine months ended September 30, 2010, the Company incurred $378,501 in a one-time patent write off cost related to its return of the Botulinum toxin vaccine license and abandonment of related patents. This cost is reflected in research and development expense in the consolidated statement of operations.

Based on the balance of licenses and patents at September 30, 2011, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
2011	$ 234,500
2012	$ 234,500
2013	$ 234,500
2014	$ 234,500
2015	$ 234,500

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 September 30, 2011, the Company had NOLs of approximately $75,000,000 for federal tax purposes and approximately $18,000,000 of New Jersey NOLs remaining after the sale of unused NOLs, portions of which are currently expiring each year until 2030. In addition, the Company had $2,948,000 of various tax credits that start 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 over a three year period. 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 its 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 2007 and 2006 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 net changes in the valuation allowance for the three and nine months ended September 30, 2011 and for the year ended December 31, 2010 were an increase of approximately $600,000 and $1,652,000, respectively, both resulting primarily from net operating losses generated. As a result of the Company's continuing tax losses, it has recorded a full valuation allowance against a net deferred tax asset.

The Company has no tax provision for the three and nine month periods ended September 30, 2011 and 2010 due to losses and full valuation allowances against net deferred tax assets.

Note 5. Shareholders' Equity

Preferred Stock

The Company has 5 million 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 nine months ended September 30, 2011:

- In sixteen separate transactions during the nine months ended September 30, 2011, the Company issued an aggregate of 1,815,780 shares of common stock under its existing Fusion Capital equity facility. The Company received an aggregate of $355,000 in proceeds which approximated the shares' fair market value on the date of issuance.

- As a result of stock option exercises, 1,596,875 shares were issued during the nine months ended September 30, 2011. The Company received an aggregate of $253,613 in proceeds from these exercises.

- As a result of granting Sigma-Tau an exclusive license to commercialize orBec® in the European territory, the Company amended the license agreement with Dr. George McDonald and issued 1,337,793 shares of Company

stock in lieu of $400,000 cash obligation. Stock price used for share calculation was $0.299, closing price at July 29, 2011.

Warrants

During 2011, the Company issued warrants to purchase 95,000 shares of common stock to consultants in exchange for their services. Expense charges of $11,184 were recorded during the nine months ended September 30, 2011, as a result of these issuances which represented the estimated fair value of the services provided.

Note 6. Commitments and Contingencies

The Company has commitments of approximately $280,000 at September 30, 2011 in connection with an agreement with Numoda Corporation for electronic data capture in connection with its confirmatory Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD that began in October 2009 and was stopped for futility in September 2011.

The Company also has 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 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.

In February 2007, the Company’s Board of Directors authorized the issuance of the following shares to Dr. Schaber, Mr. Myrianthopoulos, Dr. Brey and certain other employees and a consultant, upon the completion of a transaction, or series or a combination of related transactions negotiated by the Company’s Board of Directors whereby, directly or indirectly, a majority of the Company’s capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; 200,000 common shares to Dr. Brey; and 450,000 common shares to employees and a consultant shall be issued.

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

Note 7. Business Segments

The Company maintains two active business 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 September 30,	
	2011	2010
Revenue		
Vaccines/BioDefense	$581,943	$781,894
BioTherapeutics	5,213,919	78,623
Total	$5,795,862	$860,517
Income (Loss) from Operations		
Vaccines/BioDefense	$5,869	$(23,785)
BioTherapeutics	2,684,937	(1,237,725)
Corporate	(487,343)	(477,005)
Total	$2,203,463	$(1,738,515)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$11,247	$20,656
BioTherapeutics	47,791	28,349
Corporate	559	486
Total	$59,597	$49,491
Interest Income, Net		
Corporate	$1,411	$4,775
Stock-Based Compensation		
Vaccines/BioDefense	$16,998	$19,498
BioTherapeutics	60,487	134,908
Corporate	63,668	186,638
Total	$141,153	$341,044

	Nine Months Ended September 30,	
	2011	2010
Revenue		
Vaccines/BioDefense	$1,453,558	$1,383,788
BioTherapeutics	5,556,129	257,167
Total	$7,009,687	$1,640,955
Income (Loss) Loss from Operations		
Vaccines/BioDefense (1)	$5,921	$(748,942)
BioTherapeutics	(359,792)	(3,616,978)
Corporate	(1,098,302)	(1,089,492)
Total	$(1,452,173)	$(5,455,412)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$31,119	$57,731
BioTherapeutics	132,282	76,068
Corporate	1,641	1,471
Total	$165,042	$135,270
Interest Income, Net		
Corporate	$5,319	$8,120
Stock-Based Compensation		
Vaccines/ BioDefense	$53,830	$45,379
BioTherapeutics	346,995	189,177
Corporate	128,963	229,353
Total	$529,788	$463,909

(1) During the nine months ended September 30, 2010, the Company incurred $378,501 in a one-time patent write off cost related to its anticipated return of the botulinum toxin vaccine license and abandonment of related patents. This cost is reflected in research and development expense in the consolidated statement of operations.

	As of September 30, 2011	As of December 31, 2010
Identifiable Assets		
Vaccines/BioDefense	$591,040	$480,995
BioTherapeutics	936,546	927,973
Corporate	7,387,516	7,859,579
Total	$8,915,102	$9,268,547

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, 2010. 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 n 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 and Strategy

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 once approved by the U.S. Food and Drug Administration (the "FDA") and the European Medicines Agency. On September 15, 2011 our 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"). Our Vaccines/BioDefense business segment intends to use RiVaxTM, our ricin toxin vaccine, to support development efforts with our heat stabilization technology, and SGX202, our gastrointestinal acute radiation syndrome ("GI ARS") program, to convert from early stage development to advanced development with the assistance of ongoing government grant funding.

Our business strategy can be outlined as follows:

- evaluate the data from the recently terminated the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD") and determine how to proceed;
- use RiVaxTM to support development efforts and establish proof of concept with the heat stabilization technology, SGX205;
- complete and report data on the Phase 1/2 clinical trial for SGX201, oral BDP, in the prevention of acute radiation enteritis;
- evaluate and consider possibly initiating additional trials to explore the effectiveness of orBec®/oral BDP in other therapeutic indications involving inflammatory conditions of the gastrointestinal ("GI") tract such as GI ARS, radiation enteritis, Crohn's disease, prevention of acute GVHD, and treatment of chronic GI GVHD;
-

continue to secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;

- acquire or in-license new clinical-stage compounds for development; and
- explore other business development and acquisition strategies.

Our executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08550 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 confirmatory trial stopped for futility; further evaluating data
orBec®	Prevention of Acute GVHD	Phase 2 trial completed
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial under review
SGX201	Acute Radiation Enteritis	Phase 1/2 trial enrollment complete; Data expected in 1H 2012
SGX203	Crohn's disease	Phase 2 clinical program planned
LPM™ Leuprolide	Endometriosis and Prostate Cancer	Pre-clinical

Vaccines/BioDefense Products

Soligenix Product	Purpose	Stage of Development
SGX205	Thermostability of aluminum adjuvanted vaccines	Pre-clinical
RiVaxTM	Vaccine against Ricin Toxin Poisoning	Phase 1B trial enrollment complete;
SGX202	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 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 current confirmatory Phase 3 study was a highly powered, double-blind, randomized, placebo-controlled, multi-center trial that enrolled 140 patients. This trial is 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. This trial was stopped at the recommendation of an independent Data Safety Monitoring Board (DSMB) because it was highly unlikely to achieve the predetermined primary endpoint of efficacy based on the interim results. The data from the Phase 3 trial is currently being analyzed to determine how or whether to proceed with further development. 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.

Historical Background

Based on the data from the prior Phase 2 and Phase 3 studies, on September 21, 2006, we filed a new drug application ("NDA") for our lead product orBec® with the FDA for the treatment of acute GI GVHD. On October 18, 2007, we received a not approvable letter from the FDA in response to our NDA for orBec® for the treatment of acute GI GVHD. In the letter, the FDA requested additional clinical trial data to demonstrate the safety and efficacy of orBec®. The FDA also requested nonclinical and chemistry, manufacturing and controls information as part of this letter.

In December 2008, we reached agreement with the FDA on the design of a confirmatory, pivotal Phase 3 clinical trial evaluating orBec® for the treatment of acute GI GVHD under the FDA's Special Protocol Assessment ("SPA") procedure. An agreement via the SPA procedure is an agreement with the FDA that a Phase 3 clinical trial design (e.g., endpoints, sample size, control group and statistical analyses) is acceptable to support a regulatory submission seeking new drug approval.

Safety and Adverse Events

The frequencies of severe adverse events, adverse events related to study drug, and adverse events resulting in study drug discontinuation were all comparable to that of the placebo group in the prior Phase 2 and 3 trials. In the prior Phase 3 study, patients who remained on orBec® until Day 50 in the Phase 3 study had a higher likelihood of having biochemical evidence of abnormal hypothalamic-pituitary-adrenal axis function compared to patients on placebo. This effect was far less pronounced than those seen in patients on high dose prednisone.

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 beclomethasone dipropionate or oral BDP") Sigma-Tau, which beneficially owns approximately 26% of our shares of common stock, 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® 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 this 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.

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® into the "European Territory", as defined in the amendment. Pursuant to this amendment, we received an up-front payment of $5 million and granted Sigma-Tau an exclusive license to commercialize orBec® 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.

Total milestone payments due from Sigma-Tau under the agreement, including the amendment, could reach up to $20 million. The likelihood of achieving these milestones could be effected by the stoppage of our confirmatory Phase 3 clinical trial for orBec® in the treatment of GI GVHD at the recommendation of an independent DSMB.

We believe the potential worldwide market for oral BDP approaches $1 billion 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. orBec® represents a first-of-its-kind oral, locally acting therapy tailored to treat the gastrointestinal manifestation of GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressives to treat acute GI GVHD. Currently used systemic immunosuppressives utilized to control GI GVHD 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® and 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 US 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 are exploring the possibility of testing oral BDP (the active ingredient in orBec®) for local inflammation associated with Crohn's Disease, GI ARS, radiation enteritis, Lymphocytic Colitis, IBS, Ulcerative Colitis, among other indications.

SGX201 - Time Release Formulation of Oral BDP

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. We completed enrollment in a Phase 1/2 clinical trial testing SGX201 in acute radiation enteritis and subject follow-up is expected to be completed by the first half of 2012. 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 are 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. This program is supported in part by a $500,000 two-year Small Business Innovation Research ("SBIR") grant awarded by the NIH.

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.

Prevention of Acute GVHD

We have recently completed 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 HCT and continuing through the post-transplantation period. The trial was conducted under an investigator-initiated IND by Paul Martin, M.D., at the Fred Hutchinson Cancer Research Center and 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. Preliminary 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 subjects who developed acute GVHD with severity sufficient to require systemic immunosuppressive treatment on or before day 90 after transplantation. However, the use of orBec® 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. Further analysis of the complete dataset continues and is aimed at identifying other potential effects seen with orBec® in preventing acute GVHD.

LPM™ – Leuprolide

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

SGX205 - Thermo-stability Technology

Soligenix's Thermostability technology, SGX205, 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 SGX205 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 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, SGX205 has the potential to facilitate easier storage and

distribution of strategic national stockpile vaccines in emergency settings.

Development of SGX205 is supported by an ongoing $9.4 million National Institutes of Allergy and Infectious Disease (“NIAID”) grant utilizing Soligenix’s ricin toxin vaccine, known as RiVaxTM, where initial proof of concept at the one month time point is expected before the end of 2011. SGX205 involves stabilizing an Alum vaccine by embedding antigen-aluminum salt complexes in a stabilizing sugar matrix utilizing a process known as “glassification”. This process yields a dry and stable product which is relatively tolerant of temperature excursions and therefore able to extend shelf life. The product can then be readily hydrated to re-constitute active vaccine complexes.

Near term progress with SGX205 will allow Soligenix to seek out partnerships with companies marketing FDA/ex-US health authority approved Alum adjuvanted vaccines that are interested in eliminating the need for cold chain for their products. SGX205 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).

SGX205 is the subject of US 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 also covers thermostable vaccines for biodefense as well as other potential vaccine indications.

RiVax™

RiVax™ is Soligenix's proprietary vaccine being developed to protect against exposure to ricin toxin. 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. 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.

RiVaxTM is the subject of three issued US 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 US 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. RiVaxTM has also been granted Orphan Drug Designation by the FDA for the prevention of ricin intoxication.

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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.

SGX202 – Oral BDP for Gastrointestinal Acute Radiation Syndrome (GI ARS)

In September 2007, our academic partner, the FHCRC, received a $1 million grant from the NIH to conduct pre-clinical studies of oral BDP, also the active ingredient in orBec®, for the treatment of GI ARS. In January 2011, we released promising preliminary results from this grant-supported preclinical study of SGX202 in a canine GI ARS model. The results indicate that dogs treated with SGX202 demonstrated statistically significant (p=0.04) improvement in survival after exposure to lethal doses of total body irradiation ("TBI") when compared to control dogs. The aim of the study was to determine whether SGX202 could improve survival and GI recovery after TBI using a well-established GARS dog model. Six dogs were exposed to TBI (12 Gy administered at 70 cGy/min), and then given autologous bone marrow and SGX202 with supportive care; four dogs were used as controls and not treated with SGX202. Autologous bone marrow was given to reduce the duration and impact of the radiation-induced hematopoietic syndrome and allow for a focus on measures to treat the GI effects of TBI. SGX202 was administered two hours after TBI and daily until GI recovery (up to day 100 post exposure). Median survival post exposure in the control group was 8 days, compared to greater than 100 days in the SGX202 treated group. These results demonstrate that SGX202 has the potential to reduce the local inflammation in the radiation damaged GI tract. The principal investigator of the study is George E. Georges, M.D., Associate Member of the FHCRC. Our rights to the use of SGX202 are through our license with George McDonald, M.D.

The purpose of the studies funded by the grant was to evaluate the ability of three promising clinical-grade drugs, including oral BDP, given alone or in combination, that are likely to significantly mitigate the damage to the gastrointestinal epithelium caused by exposure to high doses of radiation using a well-established dog model. 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 type of therapy, if successful, would benefit cancer patients undergoing radiation, chemotherapy, or victims of nuclear-terrorism. In most radiation scenarios, injury to the hematopoietic, blood, system and gastrointestinal tract are the main determinants of survival.

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 all applicable outside legal and filing costs incurred in the procurement and defense of patents.

We capitalize and amortize intangibles over their expected useful life – generally a period of 11 to 16 years. We capitalize legal costs associated with the protection and maintenance of our patents and rights for our current products in both the domestic and international markets. As a late stage research and development company with drug and vaccine products in an often lengthy clinical research process, we believe that patent rights are one of our most valuable assets. Patents and patent applications are a key currency 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. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, our policy is to capitalize these costs and amortize them over the remaining useful life of the patents. We capitalize intangible assets' alternative future use as referred to in FASB ASC 350, Intangibles – Goodwill and Other and FASB ASC 730, Research and Development.

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 the carrying value of the related asset or group of assets. At this time we do not believe an impairment relating to our orBec® patent portfolio has occurred. We will assess the impairment of this asset upon the conclusion of our investigation of the confirmatory Phase 3 clinical trial for orBec® in the treatment of acute GI GVHD.

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 compensation expense, 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

Our revenues are generated from NIH grants, licensing fees and the achievement of licensing milestones. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the

grant, 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 fees and milestone revenues are recorded when earned. Recognition 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.

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 equity for the nine months ended September 30, 2011 and 2010.

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 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 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 and Nine Months Ended September 30, 2011 Compared to 2010

For the three months ended September 30, 2011, we had a net income of $2,204,874 as compared to a net loss of $1,733,740 for same period in the prior year, representing an increase in the net income of $3,938,614 primarily related to the receipt of $5,000,000 from Sigma-Tau as payment on execution of our expanded license agreement into the European territory (the "Sigma-Tau Agreement"). For the nine months ended September 30, 2011, we had a net loss of $1,446,854 as compared to a net loss of $5,447,292 for the same period in the prior year, representing a decrease of $4,000,438 primarily related to the Sigma-Tau Agreement offset by operating expenses including expenses associated with the conduct of the confirmatory Phase 3 clinical trial of orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease ("GI GVHD").

For the three and nine months ended September 30, 2011, revenues and associated costs related to NIH grants awarded in support of development of our ricin and thermo stable vaccines, orBec® and the Sigma-Tau Agreement. For the three months ended September 30, 2011, we had revenues of $5,795,862 as compared to $860,517 for the same period in the prior year, representing an increase of $4,935,345, or 574%. The increase in revenues for the three months ended September 30, 2011 was a result of the Sigma-Tau Agreement. For the nine months ended September 30, 2011, we had revenues of $7,009,687 as compared to $1,640,955 for the same period in the prior year, representing an increase of $5,368,732, or 327%. The increases in revenues were a result of the Sigma-Tau Agreement and increases in NIH grant drawdowns and the associated development work underlying them.

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We incurred costs related to grant revenues for the three months ended September 30, 2011 and 2010 of $655,125 and $779,396, respectively, representing a decrease of $124,271, or 16%. For the nine months ended September 30, 2011, costs related to grant revenues were $1,558,673 as compared to $1,402,262 for the same period in the prior year, representing an increase of $156,411, or 11%. These costs relate to payments made to subcontractors in connection with research performed pursuant to the grants. The cost changes are due to work performed on the NIH grant revenues discussed above.

Our gross profit for the three months ended September 30, 2011 was $5,140,737 as compared to $81,121 for the same period in 2010, representing an increase of $5,059,616. The increase in gross profit is directly related to the Sigma-Tau Agreement. For the nine months ended September 30, 2011, gross profit was $5,451,014 as compared to $238,693 for the same period in the prior year representing an increase of $5,212,321. The increase in gross profit is due to the Sigma-Tau Agreement and increase in grant revenues discussed above and a 2011 reimbursement of certain prior period salary costs for which there is no current period cost. Excluding the license revenue associated with the Sigma-Tau Agreement, gross profit would have been $140,737 and $451,014 for the three and nine months ended September 30, 2011, respectively.

Research and development expenses increased by $1,065,703 or 83%, to $2,342,253 for the three months ended September 30, 2011 as compared to $1,276,550 for the same period in 2010. This increase is primarily attributable to the payment of a sub-license fee of $1,012,500 in the form of Cash and Company stock to our orBec® licensor in connection with the Sigma-Tau Agreement and increased patient enrollment and activity in connection with the confirmatory Phase 3 clinical trial of orBec®. For the nine months ended September 30, 2011, research and development expenses were $5,228,779 compared to $4,025,703 for the same period in 2010, resulting in an increase of $1,203,076 or 30%. This increase is primarily attributable to the payment of a sub-license fee of $1,012,500, in the form of cash and Company stock to our orBec® licensor in connection with the Sigma-Tau Agreement, and increased patient enrollment activity in connection with the confirmatory Phase 3 clinical trial of orBec®. In 2010 we took a one time patent write-off cost of $378,501 in connection to the return of the botulinum toxin vaccine license to Thomas Jefferson University. During the three and nine months ended September 30, 2011, we incurred expenses of $850,122 and $2,563,314, respectively, in connection with the conduct of the confirmatory Phase 3 clinical trial of orBec® for the treatment of acute GI GVHD and related studies.

General and administrative expenses increased by $51,935, or 10%, to $595,021 for the three months ended September 30, 2011, as compared to $543,086 for the same period in 2010. This increase is primarily attributable to legal fees associated with completion of the Sigma-Tau Agreement. For the nine months ended September 30, 2011, general and administrative expenses was $1,674,408 representing a slight increase of $6,006, or less than 1% compared to $1,668,402 for the same period in 2010.

Financial Condition

Cash and Working Capital

As of September 30, 2011, we had cash and cash equivalents of $7,218,275 as compared to $7,451,714 as of December 31, 2010, representing a decrease of $233,439. As of September 30, 2011, we had working capital of $6,256,955 as compared to working capital of $6,101,103 as of December 31, 2010, representing an increase of $155,852 or 3%. For the nine months ended September 30, 2011, the Company’s cash used in operating activities was $730,131 as compared to $4,208,632 for the same period in 2010, representing a decrease of $3,478,501 primarily related to proceeds of $5,000,000 received from the Sigma-Tau Agreement offset by operating expenses including expenses associated with the conduct of the confirmatory Phase 3 clinical trial of orBec® in the treatment of acute gastrointestinal Graft-versus-Host disease (“GI GVHD”).

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Based on our current rate of cash outflows, cash on hand, which includes the $5,000,000 of proceeds from the Sigma-Tau Agreement, and proceeds from our grant-funded programs, 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 the following:

- The Company has instituted a cost reduction plan which has reduced headcount and will continue to reduce costs wherever possible.
- We have approximately $6.8 million in active grant funding still available to support its research programs through 2013 and beyond. The Company plans to submit additional grant applications for further support of its programs with various funding agencies.
- We will continue 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.
- We will continue to pursue Net Operating Losses ("NOL") sales in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $245,810 in proceeds pursuant to NOL sales in 2010, the Company has submitted the program application and expects to participate in the expanded program during 2011 and beyond; and
- We 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.

Expenditures

Under our budget and based upon our existing product development agreements, license agreements pursuant to letters of intent and option agreements and the discontinuation of the confirmatory Phase 3 clinical trial of orBec® in the treatment of acute GI GVHD, we expect our total research and development expenditures for the next 12 months to be approximately $4.7 million before any grant reimbursements, of which $1.8 million relates to the BioTherapeutics business and $2.9 million relates to the Vaccines/BioDefense business segments. We anticipate grant revenues in the next 12 months to substantially offset research and development expenses for the development of our Vaccines/Biodefense technology. We anticipate grant revenues in the next 12 months to partially offset research and development expenses for wind down of confirmatory 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 nine months ended September 30:

	2011	2010
Research & Development Expenses		
orBec®/oral BDP	$3,575,814	$2,367,119
RiVax™ and thermostable vaccines	1,249,564	1,038,448
BT-VACC™ (program terminated)	-	378,501
Oraprine™	-	4,500
LPM™-Leuprolide	2,577	2,577
Total	$4,827,955	$3,791,145
Reimbursed under Grants		
orBec®/oral BDP	$520,324	$224,998
RiVax™ and thermostable vaccines	1,038,349	961,857
BT-VACC™ (program terminated)	-	215,407
Total	$1,558,673	$1,402,262
Grand Total	$6,386,628	$5,193,407

Commitments

The Company has commitments of approximately $280,000 as of September 30, 2011 pursuant to its agreement with Numoda Corporation for electronic data capture in connection with the confirmatory Phase 3 clinical trial of orBec® that began in October 2009 and was stopped for futility in September of 2011.

The Company has 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 sub-lease agreement through March 31, 2012 for office space in Princeton, New Jersey. The Company was required to provide four 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.

In February 2007, the Company’s Board of Directors authorized the issuance of the following shares to Dr. Schaber, Mr. Myrianthopoulos, Dr. Brey and certain other employees and a consultant, 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: 1,000,000 common shares to Dr. Schaber; 750,000 common shares to Mr. Myrianthopoulos; 200,000 common shares to Dr. Brey; and 450,000 common shares to employees and a consultant shall be issued.

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

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

Year	Research and Development	Property and Other Leases	Total
2011	$ 160,000	$24,417	$184,417
2012	315,000	28,761	343,761
2013	75,000	5,793	80,793
2014	75,000	1,448	76,448
2015	75,000	-	75,000
Total	$ 700,000	$60,419	$760,419

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

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this quarterly report (the "Evaluation Date"). Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective.

Changes in Internal Controls

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal controls that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, such controls. However, effective as of April 26, 2011, our Controller resigned and our Chief Financial Officer, on an interim basis, assumed substantially all of the responsibilities and duties of the Controller function. On June 2, 2011, the Company announced the appointment of Joseph Warusz as Vice President of Administration and Controller.

PART II - OTHER INFORMATION.

ITEM 1A – RISK FACTORS

Our business faces significant risks. These risks include those disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as supplemented by the additional risk factor included below. If any of the events or circumstances described in the referenced risks actually occur, our business, financial condition or results of operations could be materially adversely affected and such events or circumstances could cause our actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. These risks should be read in conjunction with the other information set forth in this Quarterly Report as well as in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in our periodic reports on Form 10-Q and Form 8-K.

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.

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. The data from the Phase 3 trial is currently being analyzed.

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

In sixteen separate transactions during the nine months ended September 30, 2011, the Company issued an aggregate of 1,815,780 shares of common stock under the common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). The purchase price was calculated in accordance with the formula set forth in the purchase agreement. The Company received an aggregate of $355,000 in proceeds which approximated the shares' fair market value on the dates of issuance. The issuance of the shares was exempt from registration pursuant to Section 4(2) of the

Securities Act of 1933, as amended.

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.

November 14, 2011	By:	/s/ Christopher J. Schaber Christopher J. Schaber, PhD President and Chief Executive Officer (Principal Executive Officer)
November 14, 2011	By:	/s/ Evan Myrianthopoulos Evan Myrianthopoulos Chief Financial Officer (Principal Financial Officer)
November 14, 2011	By:	/s/ Joseph Warusz Joseph Warusz Vice President of Administration and Controller (Principal Accounting Officer)

EXHIBIT INDEX

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32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.